IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek's Memorandum in Support of Its Renewed Motion for Judgment as a Matter of Law on the Issue of Infringement, or in the Alternative, a New Trial

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I. Introduction

The sole question tried was whether or not Arthrex's FiberWire infringes Claim 1 of the Hunter 446 Patent. The only disputed issue was whether or not the coating on FiberWire "materially affects the basic and novel properties" of the invention, thereby removing FiberWire from the scope of Claim 1 because of that claim's use of the transitional phrase "consisting essentially of." The jury's non-infringement verdict cannot be sustained for either of two, independent reasons:

> (1) As a matter of law, the surface coating on FiberWire cannot materially affect the basic and novel characteristics of the invention because the patent itself discloses that surface coatings are part of the invention. Arthrex and Pearsalls cannot avoid infringement by doing exactly what the patent says one can do.
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> (2) When evidence of the effect of FiberWire's coating on the basic and novel characteristics of the invention ***as defined by the Court*** is properly considered, there is no legally sufficient evidentiary basis for the jury's verdict. The surface coating does not change the fact that FiberWire uses two dissimilar materials, braided in intertwining contact, to reap the benefits of both materials without sacrificing the properties they bring to the suture. Arthrex's evidence, directed to the affects of the surface coating on ***surface*** properties of the suture, was not directed to the Court-defined basic and novel characteristics.

II. Summary of the Argument

The Hunter 446 Patent is directed to a braided suture composed of two heterogeneous, multifilament yarns. In order to legally analyze the "consisting essentially of" language and define the basic and novel characteristics of the invention, the Court looked to the specification of the Hunter 446 Patent. It determined that "the goal of the invention" was "the mechanical blending of the two dissimilar materials," "intended to enhance the overall pliability of the device" (Ex. 1 at 13, 16-17). The Court recognized that the invention uses two dissimilar materials "to reap the benefits of each material" (Ex. 2 at 9) and defined the "basic and novel characteristics" of the invention as:

> (1) [A] surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) ***so as to*** improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture

(Ex. 1 at 18-19, emphasis added.)

There is no dispute that Arthrex's[1] FiberWire appropriates these characteristics. It is a braided suture, composed of yarns of PE and PET in direct intertwining contact, yielding a suture that reaps the benefit of each material. As the Court previously noted, FiberWire's PE contributes to the pliability, lubriciousness, and knot tie-down capacity of the suture, and its PET contributes to strength characteristics (Ex. 2 at 9). Thus, the sole issue at trial was whether or not the surface coating on FiberWire – allegedly applied to smooth out the rough surface of the braid – "materially affects" these court-defined basic and novel characteristics. This issue should have been decided as a matter of law in Mitek's favor because the disclosure in the Hunter 446 Patent reveals that coating cannot materially affect the characteristics of the invention, and the patent's disclosure should control.

As previously recognized by the Court, the inventors recognized that "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter multifilament" (Ex. 1 at 17, *citing* Ex. 3 at 1:11-14). Because fiber-to-fiber mobility is important to enhancing the pliability of a braided multifilament, the Court noted that the inventors therefore "eschewed 'any mechanism which reduces this individual fiber mobility'" (Ex. 1 at 17). For example, the patent discloses that a coating that permeates ***into*** the braid would reduce fiber mobility and adversely affect braid pliability (Ex. 3 at 1:17-21). The patent did not, however, eschew ***surface*** coatings**.** To the

[1] Unless otherwise noted, defendants Arthrex, Inc. and Pearsalls Ltd. are referred to collectively as "Arthrex."

contrary, the patent expressly disclosed that ***surface*** coatings can be applied to "further improve the handleability and knot tiedown performance of the braid" (*id*. at 6:5-8).

Undisputed evidence established that the coating on FiberWire suture is a ***surface*** coating, not a coating that permeates into the braid. Since the Hunter 446 Patent teaches that surface coatings can be applied, they are, in effect, part of the invention and cannot materially affect the basic and novel characteristics of the invention. Where, as here, the patent itself answers the question of what is or is not a material effect, the issue of material effect may be resolved as a question of law.[2] Thus, as a matter of law, the jury's verdict cannot stand, and Mitek's JMOL motion should be granted.

Alternatively, JMOL or a new trial should be granted because there is no legally sufficient evidentiary basis for the jury's verdict and/or it is against the weight of credible evidence. The *only* evidence directed to the effect of FiberWire's coating on the basic and novel characteristics of the invention as they were defined by the Court shows that the coating has no material effect—it does not affect the braiding of two dissimilar materials to reap the beneficial properties of each material without significantly sacrificing their properties.

Mitek proved that FiberWire appropriates these very basic and novel properties. It uses two dissimilar materials, PE and PET, in intertwining contact, so as to reap the benefits of each material. Mitek proved that the surface coating does ***not*** do what the Court recognized was "eschewed" by the Hunter 446 Patent, namely, reduce "individual fiber mobility." The surface coating does ***not*** bond the PE and PET fibers together or impede fiber mobility, so the final braided structure is able to have the benefits of each of the constituent materials (e.g., strength, lubricity), without significantly sacrificing their properties.

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[2] *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239-40 (Fed. Cir. 2003).

Arthrex did not focus its evidence on the Court-defined basic and novel properties. Instead, it created a smokescreen by emphasizing the unremarkable fact that FiberWire's *surface* coating enhances the suture's *surface* properties (e.g., friction, chatter, knot run down, knot security). But that evidence is not on point. The only evidence presented at trial that addressed the effect of FiberWire's coating on the relevant characteristics of the invention is the evidence that Mitek presented, and it compels a verdict contrary to that rendered by the jury.

Arthrex's witnesses and counsel stated repeatedly at trial that surface coatings are universally applied to commercial braided sutures to smooth out the rough surface of the braids. If applying a surface coating to the FiberWire braid to enhance its handleability (which Arthrex says is "standard" for any commercial, braided suture) removes FiberWire from the scope of the Hunter 446 Patent, then the patent is not worth the paper it is written on. That would be an absurd result, particularly here, where Arthrex appropriated the basic and novel properties of the invention claimed in the patent, and the patent not only expressly teaches that the claimed sutures can be coated to enhance handleability, but the "consisting essentially of" language was added to exclude not coatings but certain bioabsorbable fibers from the braid (Ex. 1 at 15).

III. The Law

A. Judgment as a Matter of Law Under FED. R. CIV. P. 50

Fed. R. CIV. P. 50(a) provides that if a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may resolve the issue against the party and grant a motion against the party on a claim or defense that, under the controlling law, can be maintained or defeated, only with a favorable finding on that issue. *Cardona-Martinez v. Rodriguez-Quinones*, 444 F.3d 25, 28 (1st Cir. 2006); *TA Insts., Inc. v. Perkin-Elmer Corp.*, C.A. No. 95-545-SLR, 1998 U.S. Dist. LEXIS 19548, *5, 17 (D. Del. Dec. 7, 1998) *aff'd in part*, No.

99-1358, 2000 U.S. App. LEXIS 12024 (Fed. Cir. June 1, 2000) (Exs. 4 and 5) (patentee's JMOL motion granted where record revealed no evidence that would support conclusion that accused device was non-infringing). Under FED. R. CIV. P. 50(b), a movant may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of the judgment. On a renewed motion under FED. R. CIV. P. 50(b), a court may order a new trial or direct entry of judgment as a matter of law.

B. Granting a New Trial Under FED. R. CIV. P. 59(a)

Under FED. R. CIV. P. 59(a), a court may grant a new trial on an issue after a jury trial for any of the reasons for which new trials have been granted in actions at law in the courts of the United States. For instance, a new trial may be granted and a jury's verdict set aside "if the verdict is against the weight of the credible evidence or results in a blatant miscarriage of justice." *Grashman Co., Ltd. v. General Elec. Co.*, 993 F. Supp. 25, 27 (D. Mass. 1998). When, as here, a trial "deals with a subject matter not lying within the ordinary knowledge of jurors a verdict should be scrutinized more closely by the trial judge than is necessary where the litigation deals with material which is familiar and simple." *Lind v. Schenley Indus., Inc*., 278 F.2d 79, 90-91 (3d Cir. 1960).

IV. Background

A. The Hunter 446 Patent

As this Court has previously recognized, the invention claimed in the Hunter 446 Patent is based on mechanically blending two different materials in direct intertwining contact so as to get the benefit of each material (Ex. 1 at 16-18; Ex. 2 at 5-6). This is described in the patent, as inventor, Dr. Mark Steckel, explained to the jury.

Dr. Steckel explained that prior suture developers had attempted to improve the properties of braided sutures, but had been unsuccessful because they failed to appreciate the

importance of fiber-to-fiber friction or mobility – *i.e.*, the effect of fibers in the suture moving against each other (Ex. 3 at 2:14-28; Ex. 6 at 159:5-16). Dr. Steckel explained that he and his co-inventors set out to "combine two materials together in the right way to get the benefits of both and achieve in this case strength and pliability and knot security" (Ex. 6 at 158:8-25; 159:5-16). He testified that they selected materials that they "thought were dissimilar and had . . . two sets of properties that [they] we're [sic] looking for, one being kind of slippery, the other in this case for this example being more strong" (*id.* at 158:23-159:2). The inventors discovered that, by incorporating a slippery material as an "internal lubricant" into the "structure," and combining that with a strong material, they could get a strong yet handleable and pliable suture (*id.* at 159:20-160:6). They could tailor the physical properties of the braid by varying the type and proportion of yarns used in the braid (Ex. 3 at 2:58-62; Ex. 6 at 165:16-166:3).

Dr. Steckel also explained how the Hunter 446 Patent disclosed that the braided sutures of the invention could optionally be coated "to further improve the handleability and knot tiedown performance of the braid" (Ex. 3 at 6:5-8; Ex. 6 at 168:22-169:16). He emphasized that the patent allows coating the ***surface*** of the braid only; a surface coating helps knot tiedown performance, but if too much coating is put on the braid, it can cause the fibers in the braid to "stick and bundle together, then you get a stiff braid again," sacrificing the very pliability properties contributed by the "slippery" or "lubricious" component of the suture (Ex. 6 at 169:19-170:15; 157:13-25; 159:20-160:6).

B. The Basic and Novel Characteristics of the Invention

The jury was asked to decide whether or not Arthrex's FiberWire products infringe Claim 1 of the Hunter 446 Patent:

U.S. Patent No. 5,314,446
1. A surgical suture ***consisting essentially of*** a heterogeneous braid composed of a first and

second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
c) optionally a core.

Arthrex did not dispute evidence Mitek presented at trial that FiberWire meets every element of this claim, with the exception of the "consisting essentially of" transitional language.[3]

"Consisting essentially of" means that claim 1 covers sutures that include the listed ingredients, as well as unlisted ingredients that do not materially affect the basic and novel properties of the invention (Ex. 8 at 892:7-14). Arthrex contended that the silicone surface coating on Arthrex FiberWire materially affected the basic and novel properties of the Hunter 446 Patent invention.

The Court defined the basic and novel characteristics of the Hunter 446 Patent invention as:

> (1) a surgical suture; (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.

(*Id*. at 891:2-9; Ex. 1 at 18-19.) The Court's construction acknowledged that the specification reveals that the goal of the claimed invention was the "mechanical blending of the two materials … to enhance the overall pliability of the device" (Ex. 1 at 16-18). The Court captured this goal in its construction of the basic and novel properties of the invention by specifically reciting that the ***constituent elements*** (the dissimilar yarns in intertwining contact) enhance the pliability and

[3] Dr. Brookstein's testimony to this effect (Ex. 7 at 236:14-241:11) was unanswered by Arthrex.

handleability of the suture ("so as to enhance…") and by focusing on the physical properties ***of those constituent elements***.

V. As a Matter of Law, FiberWire's Surface Coating Does Not Materially Affect the Novel and Basic Characteristics of the Invention

Based on the undisputed trial evidence, FiberWire's coating is a surface coating, not a coating that substantially permeates the braid and interferes with fiber-to-fiber mobility. Further, the undisputed record evidence, including the admissions of Arthrex's own technical expert, is that the Hunter 446 Patent teaches that surface coatings are optional to the invention. Accordingly, based on the undisputed record evidence, a reasonable jury could only have found for Mitek. Upholding the verdict on this record flies in the face of Federal Circuit case law holding that the patentee is entitled to define materiality and that that definition controls in the infringement analysis.

A. FiberWire's Coating is a Surface Coating

Lawson Lyon from Pearsalls, who has close to twenty years of experience with the NuSil coating that is used on FiberWire (Ex. 9 at 538:18-19; 550:6-13; 558:12-17; 559:3-25; 560:21-23), admitted that FiberWire's coating is bonded "***onto***" and "cured ***onto the surface*** of the braid" (*id.* at 554:19-22; 549:25-550:5, emphasis added). He explained that the amount of coating is kept small by squeezing off excess solution because they "don't want too much" coating on the suture (*id.* at 556:11-19).

Mitek's expert, Dr. Brookstein, confirmed Mr. Lyon's testimony that FiberWire's coating is just a ***surface*** coating (Ex. 7 at 243:21-25; 278:5-12). He personally studied FiberWire under magnification, and could see the "individuality of fibers," and that the fibers were "not bonded together" (Ex. 18, Ex. 22, Ex. 23; Ex. 7 at 270:16; 272:16-19; 386:5-9). Dr. Brookstein explained that if FiberWire's coating had substantially permeated into the braided structure, it

would be visible because there would be areas where the fibers would be stuck together (Ex. 7 at 272:22-24). Further, as Dr. Brookstein explained, his photomicrograph of the uncoated FiberWire (Ex. 24) looked similar to the coated FiberWire because the fibers in both samples showed up as individual fibers that were not bound together by any kind of coating (Ex. 7 at 267:13-18).

Dr. Brookstein also confirmed that FiberWire's coating is just a ***surface*** coating by personally studying Pearsalls' manufacturing line for FiberWire (*id*. at 229:14-21; 278:5-12). He testified that the PE/PET braid is twice passed through a bath of silicone (coating polymer) in xylene (organic solvent) at a rate of about one foot per second, excess silicone/xylene solution is wiped off by passing the braid through a clamped pressure pad ("like a squeegee"), and the braid is dried in an oven (*id*. at 230:14-234:12). Notably, this is the exact procedure disclosed in the Hunter 446 Patent for applying the optional surface coating:

> For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent.

(Ex. 3 at 6:8-11.) Following the coating process, only 4.8% by weight of the final FiberWire suture is silicone coating (Ex. 7 at 260:18-22).

Arthrex's expert, Dr. Mukherjee, tried to suggest that some coating ***could*** have permeated the FiberWire braid; however, he never offered an opinion in that regard, never provided any evidence to rebut Dr. Brookstein's evidence or Mr. Lyon's testimony that the coating on FiberWire is a ***surface*** coating only, and even admitted that his testimony that the coating "could" have permeated the braid was speculation (Ex. 10 at 741:9-742:23)[4]

[4] The trial transcript at 742:10 (Ex. 10) mistakenly reads "stipulation" rather than "speculation."

B. The Hunter 446 Patent Allows *Surface* Coatings

There is no dispute that the Hunter 446 Patent expressly teaches one of ordinary skill in the art that ***surface*** coatings may optionally be applied to the braided sutures claimed in the patent, in other words, they are part of the invention:

> ***If desired***, the ***surface*** of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating ***to further improve*** the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.
>
> If the ***surface*** of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

(Ex. 3 at 6:5-21, emphasis added.)

Three witnesses, who meet the agreed-upon standard for one of ordinary skill in the art, all agreed that the Hunter 446 Patent discloses that surface coatings can be applied to the inventive braids (Ex. 11 at 248:8-249:18; 705:23-706:7). Dr. Steckel, one of the inventors, and Dr. Brookstein both testified that the "if desired" language meant that coatings were "optional" (Ex. 6 at 168:22-169:16; Ex. 7 at 279:8-18). Dr. Mukherjee, Arthrex's technical expert, agreed, admitting that the Hunter 446 Patent teaches that a coating could be used "if desired" (Ex. 10 at 786:18-22). He explained "if desired" as follows:

> Yeah, *I can go to Detroit or I can go to New York, whatever you want to do*, but it does not say that it is required to put a coating, so it's not – it's not really emphasizing the need for coating in this sentence.
>
> Q. [sic] It's saying you can it, or you don't have to do it, right?
>
> A. *Right, so it's, like do it or you don't do it.*

(*id*. at 786:18-25, emphasis added.) He also confirmed his earlier deposition testimony that, with respect to coating, the Hunter 446 Patent teaches "you can if you want to" (*id*. at 787:11-17).[5]

C. Materiality Should be Decided as a Matter of Law

The sole infringement issue is whether or not the coating on FiberWire materially affects the basic and novel characteristics of the invention. As this Court recognized in its Claim Construction Order, the Court can decide the issue of materiality as a matter of law where the patent "specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect" (Ex. 1 at 14, citing *AK Steel*, 344 F.3d at 1240). That is precisely the case here.

The patent in *AK Steel* claimed a coated iron strip, the coating metal "consisting essentially of aluminum." The patent stated that the silicon content of the coating metal "should not exceed about 0.5%." Based on this disclosure, the Federal Circuit concluded that, as a matter of law, silicon in excess of 0.5% would materially alter the basic and novel properties of the invention. *AK Steel*, 344 F.3d at 1240. It distinguished an earlier case where it was a fact issue for the jury to determine whether or not the amounts of iron sulfide in the accused glass had a material effect on the basic and novel characteristics of the glass, because the patent had been silent about iron sulfide. *Id*., citing *PPG Indus. v. Guardian Indus. Corp*., 156 F.3d 1351 (Fed. Cir. 1998). The *AK Steel* Court explained:

> In this case, quite differently, the specification is far from silent regarding silicon and its material effect on the properties of the aluminum coating bath and the

[5] Arthrex's attempt to rehabilitate Dr. Mukherjee by directing him to the statement in the patent, "However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated, saving expense as well as avoiding the associated braid stiffening" (*id*. at 788:1-23) feel short. His testimony that this statement "discourages" the use of coating is simply not credible, as the language says "may be eliminated," not "should be eliminated," and ignored the "if desired" language.

> resultant coated steel; as explained above, the specification directly speaks to and conclusively answers that question.

Id.[6]

As in the patent in *AK Steel*, the Hunter 446 Patent "directly speaks" about ***surface coatings.*** As Arthrex's own expert admits, the patent teaches that "*[I]t's like do it or you don't do it*." Coatings are expressly allowed; since they are allowed, they cannot materially affect the basic and novel characteristics of the invention.[7] As a matter of law, since there is no dispute that the FiberWire coating is a ***surface coating*** as expressly allowed by the patent, this Court should grant Mitek's motion for JMOL. As a matter of law, FiberWire cannot avoid infringement by including an element that the patent expressly teaches may be included.

D. Arthrex's Reliance on Coatings on Other Sutures Proves Mitek's Point

Arthrex witnesses testified that surface coatings on multifilament braided sutures are commonly applied to improve handleability properties because the surface of a braided suture is rough (Ex. 12 at 450:22-451:6; 454:22-455:1; Ex. 10 at 707:13-17; 708:9-13; 709:4-9; 712:9-11; 716:14-717:1; 738:22-25; 753:11-13; 779:3-6). As Arthrex's marketing manager, Mr. Benavitz, testified, "All braided suture, to my knowledge, or 99 percent of it is coated. It's standard practice. It's known" (Ex. 13 at 484:5-6). Even the patent mentions that coatings are "universally" recognized on braided sutures (Ex. 3 at 1:29-31). If one were to believe Arthrex's

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[6] The Federal Circuit reiterated this proposition in *AFG Indus., Inc. v. Cardinal IG Co., Inc*., 239 F. 3d 1239 (Fed. Cir. 2001). In *AFG*, the asserted patent disclosed that an unlisted ingredient, an interlayer, did not have a material affect if it improved adhesion but did not substantially affect the optical properties. *Id.* at 1242. The Federal Circuit specifically adopted the materiality standard set forth in the patent itself. *Id.* at 1252.

[7] The fact that the patent in *AK Steel* taught not to use more than 5% silicon, while the Hunter 446 Patent teaches that coatings are optional, is an immaterial distinction. The salient point is that the Hunter 446 Patent teaches what may, or may not, be done with respect to coating the heterogeneous braids of the invention – rather than being silent on the issue - and, like *AK Steel*, that teaching controls the question of material effect.

position that, by using the transitional phrase "consisting essentially of," the inventors excluded all surface-coated sutures from the scope of their invention, the nonsensical result is that their patent could never cover any commercial braided suture (Ex. 6 at 169:13-16). That cannot be the case, especially where, as here, the accused product indisputably appropriates the basic and novel characteristics of the invention and uses a surface coating for the very purpose taught in the patent.

As a matter of law, FiberWire's surface coating does not materially affect the basic and novel properties of the Hunter 446 Patent invention, and Mitek asks for judgment as a matter of law that FiberWire infringes Claim 1 of the patent.

VI. Viewed in the Context of the Basic and Novel Characteristics of the Invention *as Defined by the Court,* There is no Legally Sufficient Evidentiary Basis for the Jury's Verdict and it is Against the Weight of Credible Evidence

Alternatively, JMOL or a new trial should be granted because the jury's verdict is not based on legally sufficient evidence and is against the weight of credible evidence. Mitek's evidence focused on what was legally relevant to analyzing the "consisting essentially of" element, i.e., the basic and novel characteristics of the invention ***as defined by the Court.*** These were, in short, braiding two dissimilar materials to reap the benefits of each material without significantly sacrificing their properties**.** Arthrex's evidence did not focus on these characteristics at all but was instead directed to the unremarkable fact that FiberWire's surface coating enhances the suture's handleability properties. Because the only relevant evidence of record fails to support the jury's verdict, the verdict cannot stand.

A. Mitek's Evidence Showed That FiberWire's Coating Does Not Affect the Basic and Novel Characteristics

Mitek presented evidence, not disputed by Arthrex, that FiberWire's coating has no effect on parts (1), (2),and (3) of the Court's definition of the basic and novel characteristics of the

Hunter 446 Patent invention ("(1) a surgical suture; (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set") (Ex. 7 at 244:9-246:13). As explained below, Mitek also presented evidence that FiberWire's coating does not affect part (4) of the Court-defined basic and novel properties – "so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture."

1. FiberWire Appropriates the Basic and Novel Characteristics of the Hunter Invention

a) The Constituent Elements, PE and PET, Contribute to Pliability and Handleability Without Sacrificing Physical Properties

There is no dispute that the constituent elements of FiberWire – PE and PET yarns – contribute to form a braided structure that has improved pliability and handleability without sacrificing physical properties of the constituent elements, just as taught in the patent. Donald Grafton, the scientist who developed FiberWire, testified that it was the mechanical blending of PE and PET yarns that yielded a suture with greatly enhanced properties (Ex. 14 at 197:18-198:7; 199:20-200:1).

Before Arthrex developed FiberWire, Arthrex sold two braided homogeneous polyester (PET) sutures, each of which had problems (*id*. at 191:3-10; 191:12-17; 192:24-193:1; 193:19-20). The first polyester (PET) suture was not "compliant," and the second polyester (PET) suture broke when being handled and, at least according to one surgeon, "suck[ed]" (*id*. at 191:12-17; 195:19-196:13). Originally, Mr. Grafton sought to solve the problem with a *homogeneous multifilament PE suture*. But he found that this suture had a different problem; it would not hold a knot (*id*. at 197:12-17). Thus, Mr. Grafton decided to form a *heterogeneous multifilament braided suture* of PE and PET, an idea that he claims Dr. Burkhart, a surgeon,

thought was a "killer idea" (*id*. at 197:18-198:1). He found that this heterogeneous suture, which became FiberWire, overcame the disadvantages of the homogeneous sutures, and that it had "superior tensile strength and greater knot strength than any competitive product out on the market" (*id*. at 198:2-7). Mr. Grafton admitted that he tried to optimize FiberWire's properties by mechanically blending the PE and PET (*id*. at 197:19-21; 204:4-205:18), just as taught in the 446 Patent (Ex. 3 at 2:58-66).

In fact, upon review (in connection with summary judgment briefing) of the same Grafton testimony about FiberWire's development that was presented to the jury, the Court concluded:

> [T]he evidence in the record establishes that UHMWPE in FiberWire contributes, at least in some degree, to the pliability, lubriciousness, and knot tie-down capacity of the suture. Similarly, as defendants' expert concedes, PET, which is dissimilar from UHMWPE, also contributes to the strength characteristics of FiberWire. ***In sum, FiberWire achieves the same results as the '446 Patent, and it does not do so in a substantially different way***.

(Ex. 2 at 10, emphasis added.)

b) The Intertwining Contact of Multifilament Yarns Allows Their Contribution to Pliability and Handleability

Dr. Brookstein explained that the intertwining contact of the PE and PET yarns allows the braid to reap the benefit of their dissimilar properties:

> Q. So how does FiberWire's pliability, when you look at FiberWire's pliability, what are the things that are contributing to its pliability?
>
> A. Because – well two things are happening One, because you're allowing the PE multifilament yarns, the fibers within themselves can slip, that decreases the pliability. And then because of the intertwining contact, you have a chance for the actually multifilament of the PET to slip relative to the other yarns. So it's helping you in two ways, but it's all based on the slipperiness of the PE.

(Ex. 7 at 258:9-18.)

Dr. Brookstein explained that the pliability of FiberWire is a function of "the pliabilities of all the individual filaments, each individual fiber contributed to the bending, and then you add all the individual pliabilities together to get a total pliability" (*id*. at 250:8-9; 256:17-257:3; 254:13-19). He discussed how pliability of the FiberWire braid is "based on the slipperiness of the PE" (*id*. at 258:9-18). This is the suture's "internal lubricant," as Dr. Steckel described (Ex. 6 at 159:5-160:6). Dr. Brookstein explained that the pliability is also due to the braid structure, which allowed fiber-to-fiber mobility (Ex. 7 at 257:14-25; 258:9-18). He noted that, if the fibers are bonded to one another and prevented from moving, "you're going to get back up to a very stiff structure" (*id*. at 257:12-21), but in the FiberWire structure "where there's lubricity or slipperiness between the fibers, [they] can slip, and you get the benefit of the multifilament pliability" (*id*. at 258:9-18).

2. The Surface Coating on FiberWire Does Not Materially Affect The Contribution of the Intertwined PE and PET Yarns to Pliability and Handleability and Does Not Significantly Sacrifice Their Physical Properties

Dr. Brookstein explained why FiberWire's surface coating does not have a material affect on part (4) of the Court's definition of the basic and novel characteristics of the invention, namely, "so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture" (*id*. at 259:9-14; 259:18-260:6).

Specifically, Dr. Brookstein analyzed FiberWire under a scanning electron microscope and testified that he saw individual multifilaments in direct intertwining contact. As he explained, the coating was not getting into the structure to bond the fibers together and did not interfere with the direct intertwining contact (*id*. at 272:2-273:8; 276:8-13; Ex. 18). Indeed, he determined that less than 5% of the FiberWire suture weight was coating (Ex. 7 at 260:18-22). He testified that:

> Once I observed that the coating was not getting inside the structure and bonding these fibers together, then I knew those fibers could act individually; and if they acted individually, it would be pliable.
>
> Q.: Now, does that go back to what we talked about before, the multifilament pliability and how that works?
>
> A.: Yes. These operate as multifilament structures where there is lubricity and there's freedom of motion between the fibers.

(*Id*. at 276:9-277:2.) Dr. Brookstein explained that a "[c]oating *can* have a material effect if it gets inside and bonds all these together," but that FiberWire does not have that type of coating (*id*. at 277:9-16). Because the fibers maintain their individuality there is nothing that in any way detracts from the ability of the PE and PET yarns to contribute their physical properties to the final suture.

This is borne out by Dr. Brookstein's analysis of Pearsalls' own pre-litigation, quality control test data for FiberWire suture, before and after coating. Dr. Brookstein explained that the results of testing for over 300 batches showed that there was no material difference in the knot strength *or* pliability of uncoated vs. coated FiberWire suture (Ex. 19; Ex. 7 at 301:16-304:14). In fact, Arthrex's marketing materials for commercial coated FiberWire touts it as having "greater strength" and "superior strength … unequaled in orthopaedic surgery" (Ex 20; Ex. 21 at ARM10565). And Arthrex's experts testified that the coating on FiberWire actually *enhances*, rather than sacrifices, the pliability of the suture (Ex. 10 at 795:8-13; 747:24-748:3). Thus, the coating is not materially affecting the strength and pliability provided brought to the suture by PE and PET.

B. Arthrex Did Not Present Evidence on Point

Mitek presented evidence that FiberWire's coating does not materially affect the basic and novel properties of the invention – that it does not affect the ability of the PE and PET yarns to provide, by means of their mechanical blending, a suture with improved pliability and

handleability without sacrificing those constituent elements' physical properties, such as strength. ***Arthrex provided no contrary evidence.*** It presented no evidence that the coating in any way detracts from the ability of the PE and PET yarns to contribute properties to the final suture. It presented no evidence that the coating permeates the braid and adheres the yarns together, limiting fiber-fiber mobility, so that the heterogeneous yarns are restricted from bending. It presented no evidence that FiberWire's surface coating significantly sacrifices physical properties of the constituent elements.

What Arthrex did do is present evidence that FiberWire's coating is applied to smooth out the rough surface of the braid and thereby alters surface properties of the suture (Ex. 3 at 6:5-8; Ex. 12 at 454:22-455:1; Ex. 10 at 707:13-17; 708:9-13; 709:4-9; 712:9-11; 716:14-717:1; 738:22-25; 753:11-13; 779:3-6). That the surface coating has this effect is no surprise since, as Arthrex's Dr. Mukherjee testified, it is "generally accepted in the field" that coatings are used on the surface of rough, braided sutures to improve handleability (Ex. 10 at 718:9-24) and that the coating on FiberWire serves the same purpose as coatings on other braided sutures (*id*. at 718:24-719:6) (*see also*, Ex. 16 at 830:18-831:3). And Dr. Burkhart testified that "you have to have some way to smooth out the bumps, and a coating is a very tried and true tested type of way to do that" (Ex. 12 at 451:4-6). But the fact that the coating smoothes out a rough surface and enhances handleability – even if it does so to a significant extent – does not mean that the coating is affecting the basic and novel properties of the invention, ***because the basic and novel properties of the invention have nothing to do with smoothing out the rough surface of the suture to enhance handleability.*** They have to do with the mechanical blending of dissimilar materials to reap the benefits of each material, and Arthrex's evidence and argument did not address these characteristics.

The only property of the suture that Arthrex contended was "sacrificed" by the surface coating was a surface property which Arthrex's witnesses called "knot security," a measure of the force required to have a knot slide open (Ex. 15 at 625:10-629:12; Ex. 10 at 730:2-731:9; Ex. 6 at 181:12-182:4; Ex. 15 at 625:22-626:16). But Dr. Muhrkejee's testimony that the "knot security" of ***the suture*** was "sacrificed" by using the surface coating (Ex. 10 at 731:7-9) is irrelevant because it fails to address the physical properties of ***the constituent elements of the suture,*** as required by the Court's claim construction**.** It is not unexpected that making the surface of the suture more slippery, by coating it, will make a knot slip more easily, but, like the other handleability properties affected by the coating, this effect proves nothing about how the coating is affecting the constituent elements of the suture. (*See, also, id*. at 770:11-771:10; Ex. 21; Ex. 13 at 479:9-16; 481:10-482:1; Ex. 13 at 481:10-482:5; 496:9-20).

Arthrex used misdirection to improperly shift the focus from the Court's construction of the "basic and novel characteristics" of the invention which required analyzing the ***constituent elements of the suture*** to the ***suture and its surface properties***. In fact, Arthrex's expert only referred to the Court's definition of the "basic and novel characteristics" once, in response to a leading question (Ex. 10 at 703:6-9), and then went on to testify about how FiberWire's surface coating addresses the handleability "problems" arising from the rough surface of the braid. And Arthrex's counsel never once mentioned the Court's definition of the "basic and novel characteristics" in either his opening or closing argument (Ex. 17 at 65:2-83:17; Ex. 16 at 819:14-848:3). Instead, he focused the jury entirely on the tests relating to FiberWire's ***surface*** properties and launched scurrilous attacks on Mitek and its witness because they had not presented their own (irrelevant) tests on the surface properties of FiberWire (*see, e.g.*, Ex. 16 at

831:16 accusing Mitek of having presented "a lot of tricks" and *id*. at 845:12 calling Mitek's expert, Dr. Brookstein, a "trickster").

The bottom line is that FiberWire embodies the basic and novel characteristics of the invention of the Hunter 446 Patent. It uses the dissimilar PE and PET yarns, in intertwining contact, to reap the benefits of each without sacrificing the properties of each. The surface coating on FiberWire does nothing to change this. The only evidence in the record on the point of whether FiberWire's surface coating affects the ***Court-defined*** novel and basic characteristics is Mitek's evidence, and it shows that the coating does not materially affect these properties. The record does not provide a legally sufficient basis to support the non-infringement verdict. The verdict is also plainly against the weight of the credible evidence. Mitek's JMOL motion, or, in the alternative, motion for a new trial, should therefore be granted.

VII. Conclusion

For the foregoing reasons, Mitek requests that JMOL or a new trial be granted.

Dated: September 27, 2007

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

DePuy Mitek's Memorandum in Support of Its Renewed Motion for Judgment as a Matter of Law on the Issue of Infringement, or in the Alternative, a New Trial

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 04-12457-PBS
ARTHREX, INC. and PEARSALLS LTD. Defendants.	)	

MEMORANDUM AND ORDER

January 31, 2007

Saris, U.S.D.J.

INTRODUCTION

Plaintiff DePuy Mitek, which specializes in the manufacture of surgical devices, alleges that Arthrex, Inc., and Pearsalls Ltd. (collectively "Arthrex"), two of Plaintiff's competitors, have infringed U.S. Patent No. 5,314,446 ("the '446 Patent"). Broadly, the '446 patent protects a braided surgical suture with two multi-filament yarns made from different materials. Beyond this definition, though, the parties disagree as to two key terms in the '446 Patent.

DePuy Mitek and Arthrex have moved for summary judgment on the issue of infringement. After a Markman hearing, the Court defines the two contested patent terms and **DENIES** without prejudice Plaintiff's motion for summary judgment of infringement and Defendants' motion for summary judgment of noninfringement.

FACTUAL BACKGROUND

1. The '446 Patent

The patent,[1] also known as the Hunter Patent, protects a sterilized heterogeneous braided suture. Claim One recites:

> A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core

'446 Patent col.8-9 ll.63-68, 1-9 (emphasis added). The construction of the underlined terms "consisting essentially of" and "PE" are disputed.

2. Procedural History

On November 19, 2004, DePuy Mitek filed this "suture suit" against Arthrex, claiming that two of Arthrex's products - FiberWire® and TigerWire® - infringe the '446 patent. It amended its complaint on September 9, 2005 to include similar allegations

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[1]On May 24, 1994, the United States Patent and Trademark Office issued the '446 Patent, which was assigned to to Ethicon, Inc., a New Jersey based medical device company wholly owned by Johnson & Johnson. On August 9, 2004, Ethicon transferred its interest in the '446 Patent to DePuy Mitek, another Johnson & Johnson subsidiary. DePuy Mitek currently owns this patent.

against Pearsalls, the company responsible for manufacturing the materials and braids that ultimately become part of the FiberWire and TigerWire sutures sold by Arthrex.

FiberWire is a surgical suture that is formed by braiding together yarns of ultra high molecular weight polyethylene ("UHMWPE") and yarns of polyethylene terephthalate ("PET"). These yarns are braided together so that they are in direct intertwining contact with one another. The Defendants also add a silicone coating to the braided suture, which, they argue, significantly improves the handleability and pliability of the device. TigerWire, unlike FiberWire, is composed of a UHMWPE filament and a yarn of nylon. In all other material aspects, however, TigerWire is identical to FiberWire.[2] As such, this Court will refer to these products collectively as "FiberWire."

The Defendants argue that they do not infringe the patent because the UHMWPE utilized in the FiberWire suture is different from the "general purpose" PE described in Claim One. Second, the Defendants submit that the coating on the FiberWire suture removes the product from the scope of Claim One of the '446 Patent.

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[2]As part of a motion to strike, the Defendants raise the possibility that TigerWire may be sufficiently dissimilar from FiberWire so as to warrant a separate examination of the two sutures. However, the differences between the two are not relevant to this opinion, although these distinctions may ultimately prove important.

DISCUSSION

1. Claim Construction

In construing a claim, this Court must first "look to the words of the claims themselves...to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). The language of the patent claims should be given first priority in the patent construction process because "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

Terms in the patent claims "are generally given their ordinary and customary meaning." Vitronics, 90 F.3d at 1582. The Federal Circuit has held that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313 (citations omitted). This "inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id.

Despite the primary role that the plain meaning of the claim language plays in divining the subject matter of a patent, the

Federal Circuit has held that the plain language of the patents is best understood when viewed "in the context of the entire patent, including the specification." Id. Courts must examine the terms of the claim in light of the entire patent because

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention - the inventor's lexicography - must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Therefore, in interpreting a given claim term, the Court should first look to all intrinsic evidence. First, the Court consults the claims themselves, which "provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314 (quoting Vitronics, 90 F.3d at 1582). By examining "the context of the surrounding words of the [disputed] claim," an interpreter may properly comprehend and "determin[e] the ordinary and customary meaning of those [disputed] terms." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).

Second, the Court must properly weigh the "specification

that concludes with the claims." Phillips, 415 F.3d at 1315. Therefore, the claims of a patent "must be read in view of the specification, of which they are a part." Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995)). As a consequence, the Federal Circuit has opined: "The specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Thus, the specifications should guide this Court in its study of the evidence presented by the patent.

Finally, as part of this intrinsic evidence analysis, the Court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. "Like the specification," the Federal Circuit has suggested that "the prosecution history provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317. Nevertheless, the Court has cautioned that prosecution histories, unlike other forms of intrinsic evidence, "often lack[] the clarity of the specification and thus [are] less useful for claim construction purposes." Id. (citations omitted).

In contrast to the intrinsic evidence analysis endorsed by the Court in Phillips, extrinsic evidence, "consist[ing] of all evidence external to the patent and prosecution history,

including expert and inventor testimony, dictionaries, and learned treatises," is less favored in the claim construction analysis. Markman, 52 F.3d at 980 (citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1870)). Although the Court has expressly "authorized district courts to rely on extrinsic evidence," Phillips, 415 F.3d at 1317, the Federal Court warned that such exogenous evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Therefore, the Court has resolved to "emphasize[] the importance of intrinsic evidence in claim construction" because "extrinsic evidence...is unlikely to result in a reliable interpretation of patent claim scope." Phillips, 415 F.3d at 1319.

A. Meaning of "PE"

The parties dispute the proper scope of the term "PE" in the context of the '446 patent. Plaintiff contends that PE includes any polymer formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. By contrast, the Defendants argue that the term "PE" in the claims refers to general purpose PE, which excludes UHMWPE.

Plaintiff's expert, Dr. Matthew Hermes, provided the

scientific background, which is largely undisputed. PE is formed from repeating units of the monomer ethylene, (CH_2-CH_2). (Pl.'s Markman Br. Ex. 7 at ¶ 6.) PE may be referred to as $(CH_2\text{-}CH_2)_n$, where n equals a whole number and indicates the number of repeating monomeric units of ethylene in the polymer. The "molecular weight" of a PE chain is determined by the length of the chain (i.e., how high n is). UHMWPE is composed of the same monomer unit as any other polyethylene chain, but has a longer chain of the repeating ethylene monomer than "low molecular weight" or "medium molecular weight" PE. (Id. at ¶ 7.) In other words, the building block for a suture made from UHMWPE is a very long and heavy PE chain.

Claim One recites that the first yarn is composed of a fiber-forming material "from the group consisting of" seven specific polymers, including PE. The specification is clear that "PE" means polyethylene. '446 Patent col.4 l.27. This claim does not distinguish between kinds of PE possessing different molecular weights. The patentee did not limit the definition of PE. Cf. Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1373 (Fed. Cir. 2005) (determining that the claim term "saccharide" should not be construed only to include polysaccharides having ten or less monomer units because the claim, like the specifications, did not contemplate such a limited definition).

Plaintiff has also introduced evidence that a person having ordinary skill in the art would understand PE to mean all polymers made from PE. Dr. Hermes opines: "One of skill in the art would have known that 'PE' means 'polyethylene' and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE." (Pl.'s Markman Br. Ex 7 at ¶ 9.) To support Dr. Hermes's opinion, DePuy Mitek points to several technical dictionaries stating that the term PE encompasses all polymers consisting of ethylene monomers, including UHMWPE. For instance, the Encyclopedia of Polymer Science and Engineering states that "polyethylene [is] the 'common (source-based)' name for all polymers made from ethylene." (Pl.'s Markman Br. Ex. 7, Tab B).

The Defendants, however, argue that UHMWPE is a rigid and inflexible synthetic compound that would never enhance the pliability or lubricity of a suture.[3] As one of Arthrex's experts, Dr. Debi Prasad Mukherjee, argues:

> In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that,

---

[3]Plaintiff has introduced evidence that UHMWPE is lubricious. (See Plaintiff's Ex. 9 at 51:15-55:5). The parties do not clearly explain the difference, if any, between a lubricious material and a stiff material in the context of a suture. Both appear to be related to handleability and pliability.

> generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known.

(Def.'s Markman Br. Ex. 12.) Although there is evidence that a person of ordinary skill in the art would understand that UHMWPE has different properties from other kinds of PE, Arthrex has introduced no evidence that one of ordinary skill would not understand the term PE to include UHMWPE.

Defendants argue that the prosecution history contains a disclaimer of the polymer UHMWPE, citing extensively to the discussion of the "Burgess reference" in the '446 Patent's history. (Def.'s Markman Br. Ex. 7-8.) The Burgess patent protects a type of braided fishing line that utilizes a high-tensile PE as part of its construction. In response to the rejection by the patent examiner of the suture claims based on the Burgess patent application, the applicant argued:

> One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement maybe the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact.

(DM1000196). (Emphasis in original). The applicant distinguishes Burgess: "In contrast, knot strength is not even mentioned in Burgess." (Id.) The applicant adds: "Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability....Although this thread has great strength

properties, it suffers from low elongation and, in turn, poor knot strength properties." (DM1000196). (Emphasis in original). The parties agree that "high-tensile polythene" is the European terminology for UHMWPE.

In overcoming the Burgess reference, the applicant does distinguish the suture from the fishing wire by drawing a distinction between materials used in the invention, pointing out the poor knot strength properties of high-tensile polythene. The Defendants argue that in distinguishing the heterogeneous braided suture from the fishing line composed of UHMWPE, the patentee limited the scope of its patent to ordinary general use PE. (Def.'s Markman Br. 12-13).

Plaintiff responds that the prosecution history is not a clear disclaimer of the UHMWPE. It emphasizes that the patent examiner and the applicant both routinely refer to the "high tensile polythene" described by the British Burgess patent as "polyethylene." (See, e.g., Pl.'s Markman Br. Ex. 3 at DMI000189.) By including "PE" in the list of polymers in the amended claim, Plaintiff contends, the inventors intended to include UHMWPE. Moreover, while the prosecution history does indicate that UHMWPE was not a preferred polymer because of its minimal stretchability, the applicant emphasized the distinction between the uses and purposes of the two devices:

> In view of the dissimilarities in property requirements between sutures and fishing line, there would be no

> incentive for a medical designer who wishes to improve the properties of a braided suture to study the art related to braided fishing lines. Even if he did use the teachings of fishing line art to modify a suture, then he would inevitably design an unacceptable suture.

(Pl.'s Markman Br. Ex. 3 at DMI000196-97.) In light of this language, Plaintiff's argument that there was never a clear disclaimer of UHMWPE is ultimately persuasive. See Andersen Corp. v. Fiber Composites, LLC, Nos. 05-1434, 06-1009, ____ F.3d ____, 2007 WL 188709, at *10 (Fed. Cir. Jan. 26, 2007) (citing Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1375 (Fed. Cir. 2005)) ("It is true that we have warned against importing limitations from the specification into the claims absent a clear disclaimer of claim scope.").

Pulling together all of these threads, this Court finds that an ordinary person skilled in the art of science and suture manufacturing looking to the plain language of the claim, the specification, and the prosecution history of the '446 Patent would conclude that "PE," as used in Claim 1, includes all polymers formed from a repeating ethylene monomer, including UHMWPE.

B. Meaning of "Consisting Essentially Of"

The second term disputed by the parties is the transitional phrase "consisting essentially of." Generally, three transitional terms are used in patent claims: (1) "comprising," which is an open term of transition (2) "consisting of," which is

a closed term of transition, and (3) "consisting essentially of," which is a partially open term perched between the extremes of the other two phrases. "In view of the ambiguous nature of the phrase," the Federal Circuit has opined that "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (quoting PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

To determine those "basic and novel properties of the invention," the Court must look at the specification to determine "the goal of the invention as well as what distinguishes it from prior art." AK Steel, 344 F.3d at 1239-40 (holding that a limiting statement in the specification that silicon should not exceed 0.5% was a disclaimer which had an impact upon the meaning of the phrase "consisting essentially of aluminum.") The Court must also look at the prosecution history of a patent to determine whether an unlisted ingredient was excluded from the scope of a "consisting essentially of' claim. PPG, 156 F.3d at 1355.

Construing the "consisting essentially of" language in a patent claim can "at times blur the distinction between the separate steps in an infringement analysis." AK Steel, 344 F.3d

at 1240. Where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect, the issue may be resolved as a question of law. Id. In some situations, however, whether an additional ingredient materially affects the basic and novel characteristics of a patented invention is a question of fact for a jury. See PPG, 156 F.3d at 1357 (stating that it is the province of the jury to determine whether the iron sulfide had a material affect on the basic and novel characteristics of the patented glass).

The key question of claim construction for this term in Claim One involves discerning the basic and novel properties of the heterogeneous suture. Once this determination has been made, the Court can attempt to resolve the parties' disagreement over whether the surgical coating placed on FiberWire braided suture "materially affects" the basic and novel properties of the suture described by the '446 Patent. AK Steel, 344 F.3d at 1239.

The Defendants submit that this Court should construe the claim term "consisting essentially of" as follows:

> i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.
>
> ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

(Def.'s Markman Br. 16.) By contrast DePuy Mitek suggests:

> The 'novel and basic characteristics' of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *Consisting essentially of* excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials.

(emphasis in original) (Pl.'s Markman Br. 8.)

DePuy Mitek's primary argument is that the transitional phrase was inserted to exclude certain bioabsorbable materials in the prior art from the patent claims. The prosecution history demonstrates the "consisting essentially of" language was added by amendment. In the prosecution history, the examiner originally had rejected the claims based on two references - Doddi and Kaplan - which included braids of dissimilar materials. Plaintiff argues it amended the claims to exclude bioabsorbable materials from the first and second fiber-forming materials in order to further distance itself from this prior art.

In response to the examiner's rejection for anticipation by Kaplan, the applicant stated that in Kaplan, the "sheath yarn" was a "biocompatible yarn that is bioabsorbable or semi-bioabsorbable...In one embodiment the sheath yarn could also contain a non bio-absorbable yarn of one or more chemical compositions....Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn." (DMI 1000259). (Emphasis

added). Later, the applicant again distinguishes the prior art: "Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e., PTFE) and a second set of nonabsorbable yarn (i.e., PET). (DM 1000260).[4] Id. Thus the Plaintiff argues there is a clear and express disclaimer of bioabsorbable yarns in the prosecution history. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005).

Defendants contend that the prosecution history does not support this interpretation because the patent specification provides, "The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired." '446 Patent col.3 ll.63-65 (emphasis added). Still, under the doctrine of prosecution disclaimer, Plaintiff's argument that it clearly disclaimed bioabsorbable yarns to overcome the rejection seems persuasive. Nonetheless, this debate seems largely beside the point because the issue here involves coatings, not bioabsorbable yarns.

The Defendants contend that the invention's primary basic and novel characteristic is that it improves the handleability and pliability of a suture without significantly sacrificing any physical properties of the constituent materials of the device, like strength or knot tiedown. The specifications reveal that

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[4]In addition, the plaintiff pointed out that Kaplan taught that sheath yarns listed in the invention should not be used in sheaths.

the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10. The specification points out, "Unfortunately, the prior art abounds with attempts to improve specific properties of multi-filament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multi-filament sutures almost universally possess a surface coating to improve handling properties." Id. at col. 1 ll. 26-31. It continues: "All of the attempts described in the prior art have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability." Id. at col. 2 ll. 14-17. Of significance, the specification states:

> In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties."

Id. at col.2 ll, 32-37 (Emphasis added).

Plaintiff argues that increased pliability is a property only of the preferred embodiment, pointing to the passage that states: "For example, in preferred embodiments, the heterogenous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." Id. at col. 2 ll. 50-67. As shown above, this is a myopic view of the specification, which states throughout that a primary goal of the invention is to achieve enhanced pliability and handleability. The sterilized heterogeneous braids described in this patent seek to achieve a high degree of pliability and handleability by mechanically blending together two dissimilar synthetic yarns.

Therefore, this Court concludes that the basic and novel properties of the suture described in the '446 Patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability

without significantly sacrificing the physical properties of the constituent elements of the suture.

2. Summary Judgment

As noted previously, both DePuy Mitek and Arthrex have moved for summary judgment on the issue of patent infringement. However, the summary judgment record is a mess because of the multiple motions to strike, each with extensive appendices and confusing briefing. This Court has allowed Arthrex to supplement Dr. Gitis's expert report to correct certain typographical and computational errors. Moreover, DePuy Mitek has launched a Daubert challenge to Defendants' expert report, and it is difficult to figure out the various expert opinions on the affect of the coatings on the accused devices. Accordingly, this Court will deny these cross-motions for summary judgment without prejudice.

ORDER

Plaintiff's motion for summary judgment of infringement is **DENIED** without prejudice (Docket No. 36). Defendants' motion for summary judgment of noninfringement is **DENIED** without prejudice (Docket No. 39).

All parties are ordered to submit a single brief, not to exceed 20 pages, on the summary judgment issue of patent infringement within 60 days in light of the Court's construction of the '446 Patent. The parties shall file no additional motions

to strike, and there shall be no replies or sur-replies.

PATTI B. SARIS
United States District Judge

EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 04-12457-PBS
ARTHREX, INC. and PEARSALLS LTD. Defendants.	)	

MEMORANDUM AND ORDER

July 31, 2007

Saris, U.S.D.J.

In this case about braided sutures, both parties cross-moved for summary judgment on two of Arthrex's defenses: (1) that an adhesive is added to the tips of FiberWire, which stiffens the suture, thus materially affecting the basic and novel characteristics of the invention; and (2) that FiberWire avoids infringement under the reverse doctrine of equivalents. After consideration, the Court **ALLOWS** the plaintiff's motion and **DENIES** the defendants' motion.

A. The Tipping Point[1]

Defendants state that an adhesive is added to the ends of FiberWire to stiffen the suture, prevent fraying, and help

[1] The summary judgment motions primarily focused on the effect of the FiberWire coating. The briefing on these ancillary issues was cursory. Indeed, defendants' discussion is limited to a 4-line argument in a footnote on page 18 of the brief. As such, it has arguably waived the issue.

doctors attach instruments, such as anchors, needles, and hooks, to the suture. Arthrex argues that the addition of this material, which covers approximately 1 inch of both ends of the FiberWire device, supports a non-infringement defense, because these tips improve the suture's handleability by facilitating attachment to instruments in a manner that materially affects the basic and novel characteristics of the suture.

Plaintiff responds that the presence of these tips is irrelevant as a matter of law; it argues that "as long as 36 or 16 inches of FiberWire infringes," then the entire suture infringes. (Pl.'s Mem. Supp. Summ. J. 10.) In support of this argument, plaintiff points to A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703 (Fed. Cir. 1983) (citing Temco Elec. Motor Co. v. Apco Mfg. Co., 275 U.S. 319, 328 (1928)), which stated:

> It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device .... For example, a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.

See also SunTiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1336 (Fed. Cir. 1999) ("we have never required that a claim read on the entirety of an accused device in order to infringe. If a claim reads merely on a part of an accused device, that is enough for infringement."). In other words, plaintiff submits that Arthrex cannot avoid infringement simply

by adding some adhesive onto the ends of the suture.

Arthrex retorts that the cases upon which DePuy Mitek relies do not apply here since they all address patents containing the open term of transition, "comprising," whereas the '446 Patent contains the partially open transitional phrase, "consisting essentially of." The term "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003). The "consisting essentially of" language in a patent claim can at times blur the distinction between the separate steps in an infringement analysis (claim construction and comparison of the construed claim to the accused device or method). Id.

Undeterred, DePuy Mitek offers two additional cases, both of which involve patents with the restrictive closed terms of transition, "consisting of." This transition term "does not exclude additional components or steps that are unrelated to the invention." See Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1360-61 (Fed. Cir. 2006) (emphasis added) (holding that additional element "unrelated' to the claimed invention did not preclude infringement even where "consisting of" transitional phrase is used). In determining whether an unrelated additional component is excluded from the scope of the claim, a court must "determine what is limited by the 'consisting of' phrase."

Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331-1332 (Fed. Cir. 2004) (reversing summary judgment of noninfringement because addition of a spatula was unrelated to the claimed invention of a for a kit "consisting of" certain chemicals). Again, plaintiff's cases are not entirely on point because they involve a different transitional phrase.

To resolve this debate, the Court must return to the claim construction. In an earlier Markman opinion, I determined that the basic and novel characteristics of the '446 Patent were: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture. DePuy Mitek, Inc. v. Arthrex, Inc., No. 04-12457-PBS, slip op. (D. Mass. Jan. 31, 2007).

Here, the parties have not asked the Court to address the issue of the tipping as a matter of claim construction although this issue seems to be in the gray area between claim construction and infringement. The patent itself is silent regarding tipping. Whether or not defendants' suture infringes plaintiff's patent hinges on whether these tips materially affect the basic and novel characteristics of the suture described in the '446 Patent, notably the characteristics of "handleability"

and "pliability" that were identified in the earlier Markman opinion.

Arthrex points to deposition testimony to suggest that the tips materially affect the basic and novel characteristics: Kevin Grieff stated: "Tipping is to make the suture rigid so you can pass it through instruments." (Def.'s Ex. 30, 53:25-54:2.) Shelby Cook Kornbluth testified: "The original intent of tipping the suture is so that you can -- that the end of the suture is stiff enough to insert into a needle to attach or for a surgeon to put through a free needle so that they can use a suture without a needle on it." (Def.'s Ex. 14, 120:1-6.) Ilya Koyfman reported: "The tipping is a relatively rigid polymeric substance which allows for insertion of a suture into the needle." (Def.'s Ex. 16, 106:5.) Plaintiff, meanwhile, concedes that FiberWire has adhesive tips that perform some function, but notes that they are small and commonly used throughout the field. Pointing to brochures from Arthrex, plaintiff argues that Arthrex's tips are so small as to be insignificant to the product. Plaintiff also notes that these tips are primarily used for attaching the suture to anchors and needles. As such, they cannot improve pliability or handleability as described in the specification, primarily knot tie-down.

The specification reveals that the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention"

section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10 (emphasis added).

The invention did not relate to how the suture handled when it was being attached to another surgical object, like a needle or an anchor. Accordingly, this Court finds as a matter of law that the tips do not materially affect the basic and novel characteristics of the '446 Patent that I identified in my Markman opinion. Thus, summary judgment for plaintiff is appropriate.

B. Reverse Doctrine of Equivalents[2]

In 1950, the Supreme Court in Graver Tank & Mfg. Co. v.

[2] The defendants raise their reverse doctrine of equivalents argument in a footnote to their brief. As such, the briefing on this issue is quite spartan.

Linde Air Products Co., first articulated the "reverse doctrine of equivalents" as a defense to patent infringement, stating that:

> where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement

339 U.S. 605, 608-609 (1950). Courts interpreting Graver have left little guidance on the parameters of the reverse doctrine of equivalents. One recent case, Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002), undercuts this doctrine as an "anachronistic exception," noting "[n]ot once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents." Id. Explaining that "when Congress enacted 35 U.S.C. § 112, after the decision in Graver Tank, it imposed requirements for the written description, enablement, definiteness, and means-plus-function claims that are co-extensive with the broadest possible reach of the reverse doctrine of equivalents," the Federal Circuit suggested that this arcane defense was largely disfavored because it had been subsumed by more comprehensive legislation. Id. (citations omitted).

Despite this ominous language regarding the continuing

viability of the reverse doctrine of equivalents defense, Graver has only one foot in the grave. The Federal Circuit has recently instructed that the reverse doctrine of equivalents "is equitably applied based upon underlying questions of fact." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1351 (Fed. Cir. 2004). The accused infringer must prove that although the asserted claim literally infringes on the accused device, "it has been so changed that it is no longer the same invention." Id. The court cautioned that "it is error to conduct infringement analyses [based on this doctrine] in a vacuum, without reference to the claims at issue." Id. (rebuffing the defendant's attempt to avoid infringement under the doctrine, even though "the method by which [defendant] controls [DNA] transcription is not identical" to the transcription methods taught by the patent and the DNA promoter was in a different location).

Arthrex, relying on its expert Dr. Mukherjee, points out:

> The specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and pliability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the precise opposite. UHMWPE (the alleged first fiber-forming material) is added for strength and PET (the alleged second fiber-forming material) is added to improve knot tying -- a well-known handleability characteristic.

(Def.'s Mem. Supp. Summ. J. Ex. 31 at 18.) Because FiberWire ostensibly turns the patent on its head, Arthrex argues that its

suture is so far changed in principle from the patented article that it performs the same or a similar function in a substantially different way.

As a preliminary matter, the specification discusses the role of the first and second set of yarns in a preferred embodiment. '446 Patent col.4 ll.9-40. The claim itself does not require that the two sets of yarns have the properties described by Dr. Mukherjee. Moreover, Mr. Grafton, Arthrex's former vice-president and designer of FiberWire, who testified that PET, one of the materials from the second group of fiber-forming threads, makes FiberWire stronger because, without it, a PE-only suture had knot slippage. (Pl.'s Mem. Supp. Summ J. Ex. 12 at 51:22-52:15; 53:20-54:5.) Grafton also testified that FiberWire's UHMWPE is lubricous. Id. at 52-53. Therefore, it improves compliance, lubricity, and fiber-to-fiber movement, and therefore contributes to handling and pliability properties. (Id. at Ex. 6 at ¶¶ 38, 40, 41, 45), just as the '446 Patent teaches. Thus, from this undisputed evidence, it appears as if the characteristics of the two threads in FiberWire, UHMWPE and PET, both contribute to the strength and handleability of the suture as provided in the claim construction. In this manner, DePuy Mitek argues that FiberWire achieves the same result (a braided suture that uses two dissimilar materials to reap the benefits of each material) in a sufficiently similar manner.

This Court finds that DePuy Mitek's argument is the better

one. First, while it is undisputed that UHMWPE is stronger than generic PE, the evidence in the record establishes that UHMWPE in FiberWire contributes, at least in some degree, to the pliability, lubricousness, and knot tie-down capacity of the suture. Similarly, as defendants' expert concedes, PET, which is dissimilar from UHMWPE, also contributes to the strength characteristics of FiberWire. In sum, FiberWire achieves the same result as the '446 Patent, and it does not do so in a substantially different way.

ORDER

Plaintiff's motion for summary judgment [Docket No. 105] on the reverse doctrine of equivalents and on defendants' tipping argument is **ALLOWED**. Defendants' motion for summary judgment [Docket No. 107] on these issues is **DENIED**.

S/PATTI B. SARIS
United States District Judge

EXHIBIT 3

US005314446A

United States Patent [19]

Hunter et al.

[11] **Patent Number: 5,314,446**

[45] **Date of Patent: May 24, 1994**

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

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2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

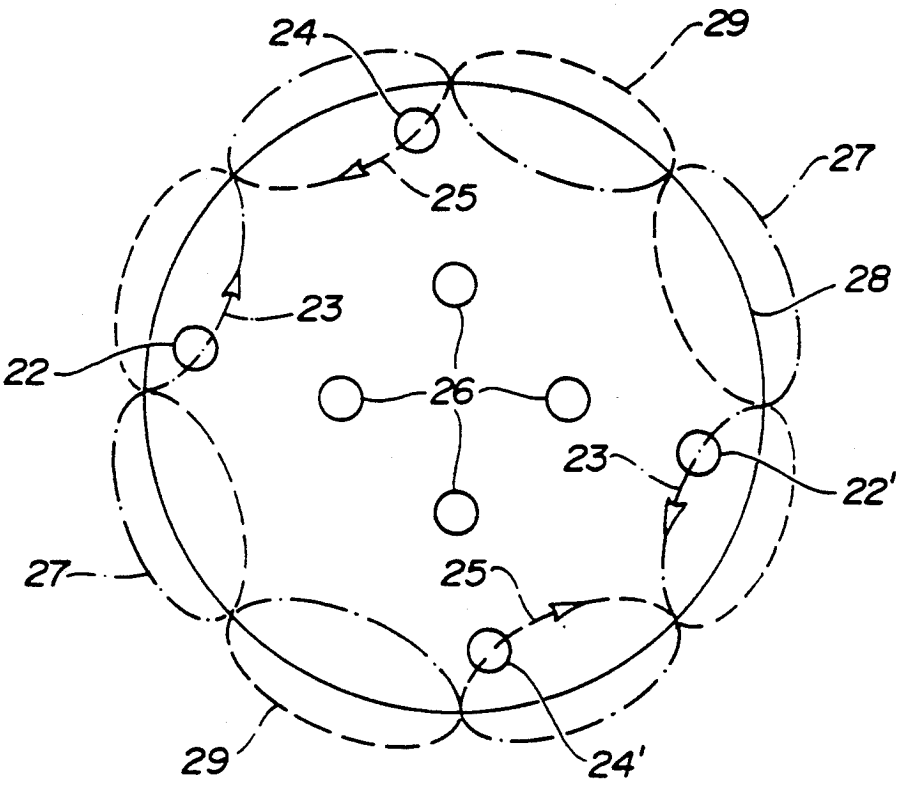


FIG-2

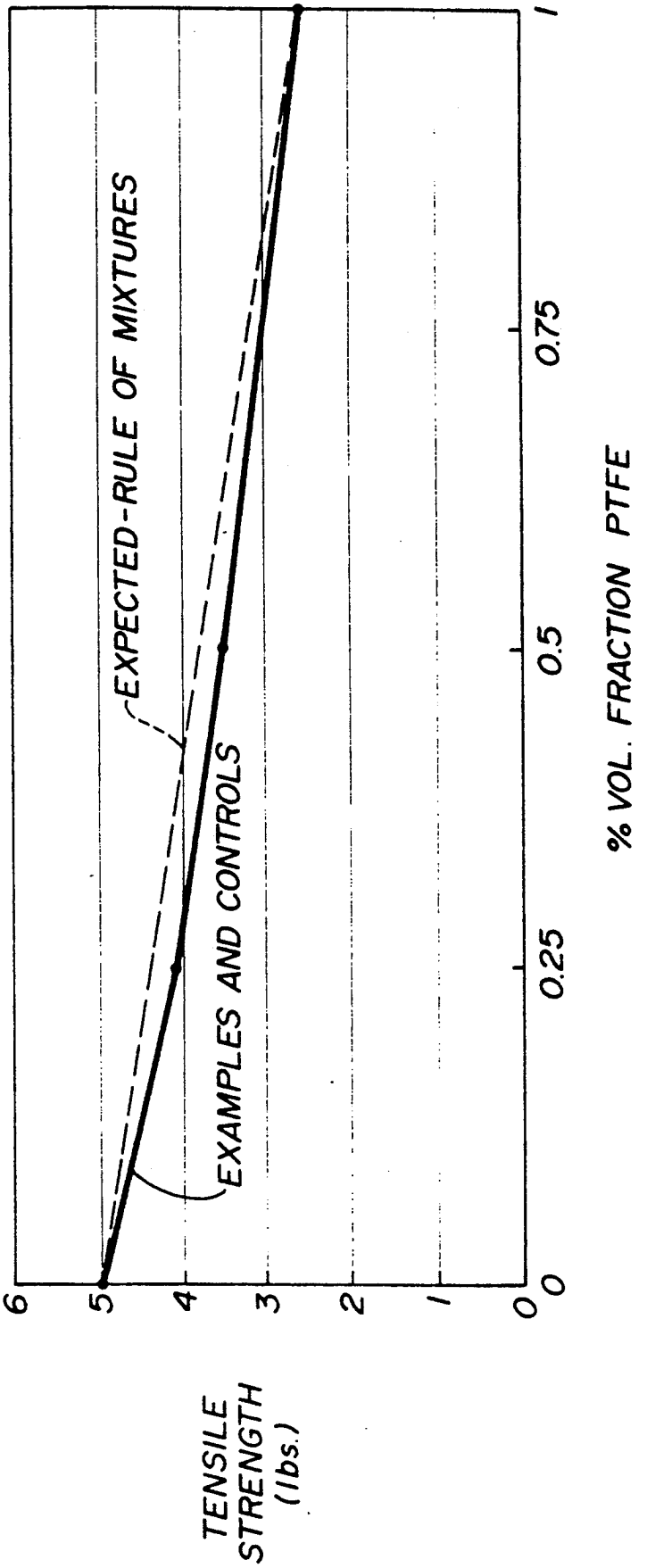
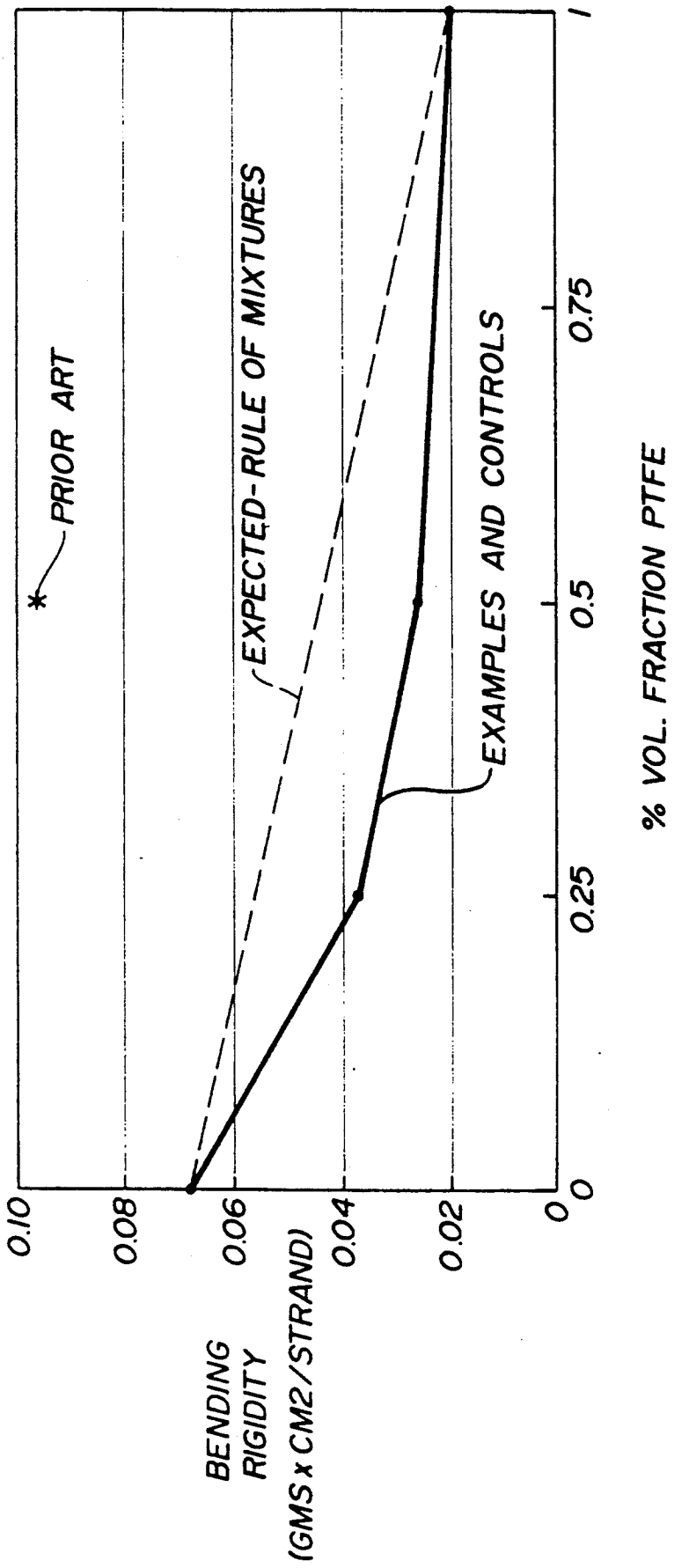

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. **2** is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. **3** is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. **1** for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers **22**, **22'** and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)\,(P_a)+(Vf_b)\,(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim **1** wherein the suture is attached to a needle.

3. The surgical suture of claim **1** wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim **3** wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim **4** wherein the first set of yarns is PTFE.

6. The surgical suture of claim **5** wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim **6** wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim **1** wherein the second set of yarns is PET.

9. The surgical suture of claim **8** wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim **9** wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim **1** wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim **8** wherein the suture is attached to a needle.

* * * * *

EXHIBIT 4

LEXSEE 1998 US DIST LEXIS 19548

TA INSTRUMENTS, INC., Plaintiff, v. THE PERKIN-ELMER CORPORATION, Defendant.

C.A. No. 95-545-SLR

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1998 U.S. Dist. LEXIS 19548

December 7, 1998, Decided

NOTICE: [*1] FOR ELECTRONIC PUBLICATION ONLY

DISPOSITION: Plaintiff's renewed motion for JMOL pursuant to Fed.R.Civ.P. 50(b) granted.

COUNSEL: For plaintiff: Richard K. Herrmann, Esquire, Mary B. Matterer, Esquire, Blank, Rome, Comisky & McCauley LLP, Wilmington, Delaware.

For plaintiff: Richard McMillan, Jr., Esquire, Lawrence J. Gotts, Esquire, Aslan Baghdadi, Esquire, David C. Isaacson, Esquire, Of Counsel, Crowell & Moring LLP, Washington, D.C.

For defendant: Robert K. Payson, Esquire, Joanne Ceballos, Esquire, Potter, Anderson & Corroon LLP, Wilmington, Delaware.

For defendant: Lawrence B. Goodwin, Esquire, Marc J. Pensabene, Esquire, Philip E. Levy, Esquire, Of Counsel, Orrick, Herrington & Sutcliffe LLP, New York, New York.

For defendant: David Aker, Esquire, The Perkin-Elmer Corporation, Norwalk, Connecticut.

JUDGES: Sue L. Robinson, District Judge.

OPINION BY: Sue L. Robinson

OPINION:

OPINION

Date: December 7, 1998
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Plaintiff TA Instruments, Inc. is the assignee of all rights, title, and interest in and to U.S. Patent Nos. *5,224,775* ("the *'775* patent"), *5,346,306* ("the *'306* patent"), and *5,439,291* ("the [*2] *'291* patent"). (D.I. 1, PP 9-12) Generally speaking, these patents disclose an analytical technique using a differential scanning calorimeter whereby a material is "driven . . . through a transition" by an independent physical parameter, such as temperature, in order to study the material's properties. (D.I. 1, Exs. A-D) Beginning in March 1995, defendant The Perkin-Elmer Corporation introduced and began sale of its Dynamic Differential Scanning Calorimeter ("DDSC"). (D.I. 1, P 15)

On September 7, 1995, plaintiff filed a complaint alleging, inter alia, that defendant has infringed and/or is continuing to infringe, either literally or by the doctrine of equivalents, one or more claims of the *'775*, *'306*, and *'291* patents by making, using, offering to sell, and selling DDSC instruments. (D.I. 1, P 17) Plaintiff characterizes said infringement as being "deliberate, willful, wanton, intentional and with full knowledge of the existence and validity" of its patents. (D.I. 1, P 18) On March 15, 1996, defendant filed an answer denying infringement and asserting several counterclaims and affirmative defenses. (D.I. 8) The defenses included, inter alia, that the patents are invalid for [*3] obviousness. (D.I. 8, P 28)

On January 13 through January 30, 1998, the court

held a jury trial on the issues of infringement and validity. By verdict rendered on February 2, 1998, a jury found that plaintiff had failed to prove by clear and convincing evidence that claim 17 of the *'775* patent; claims 1, 11, 21, 26, 37, and 41 of the *'306* patent; and claims 11, 38, and 88 of the *'291* patent are infringed by defendant's DDSC, either literally or by the doctrine of equivalents. (D.I. 301) The jury also found that defendant had failed to establish that these claims are invalid. (D.I. 301) Finally, the jury found that defendant's DDSC infringes, either literally or by the doctrine of equivalents, claim 73 of the *'291* patent, but that this claim is invalid for obviousness in light of the prior art. (D.I. 301)

At the close of evidence, plaintiff moved for judgment as a matter of law ("JMOL") under *Fed.R.Civ.P. 50(b)* on the issues of infringement and validity. (D.I. 313 at 2125-32) At that time, the court reserved judgement on all JMOL motions. (D.I. 313 at 2126, 2132) Currently before the court is plaintiff's renewed motion for JMOL or, alternatively, for a new trial under *Fed.R.Civ.P.* [*4] *59* on the issues of infringement, validity, willfulness, and damages. n1 (D.I. 326) Specifically, plaintiff requests entry of JMOL that (1) defendant's DDSCs infringe, both literally and under the doctrine of equivalents, claim 17 of the *'775* patent and claims 1, 11, 21, 37, and 41 of the *'306* patent; (2) defendant's DDSCs literally infringe claim 73 of the *'291* patent; and (3) claim 73 of the *'291* is not invalid as obvious in light of the prior art. (D.I. 326)

> n1 In its motion, plaintiff waives the right to further jury trial pursuant to *Fed.R.Civ.P. 39* with respect to the issues of willfulness and damages, agreeing to submit these issues to the court for determination, as long as defendant similarly agrees to waive its right. (D.I. 326) Should defendant not waive its right to further jury trial, plaintiff requests entry of judgment with respect to liability for infringement as well as immediate entry of an injunction. (D.I. 326) The court notes that defendant has opted to exercise its right to have all fact issues determined by a jury. (D.I. 333 at 31)
>
> In addition, plaintiff requests that this court (1) conditionally grant it a new trial pursuant to *Fed.R.Civ.P. 50(c)(1)* in the event of reversal of the court's JMOL and (2) grant a new trial with respect to the issues of willfulness and damages following appellate review, to the extent such issues have not been previously resolved by the parties. (D.I. 326)

[*5]

II. STANDARD OF REVIEW

By its motion for entry of JMOL or, alternatively, for a new trial, plaintiff seeks relief from an adverse jury verdict. To prevail on a renewed motion for JMOL following a jury trial, a party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)* (quoting *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)).* "'Substantial'" evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp., 732 F.2d at 893.* In assessing the sufficiency of the evidence, the court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant. See id.; *Richardson-Vicks Inc. v. UpJohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).* The appropriate inquiry is whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did. [*6] See *Dawn Equip. Co. v. Kentucky Farms, Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998)* (citing *Markman v. Westview Instruments, Inc., 52 F.3d 967, 975-76 (Fed. Cir. 1995)* (en banc)). The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp., 732 F.2d at 893.*

Likewise, in order to promote finality after trial, as well as to preserve the historical function of the jury as the trier of facts, the court "ought to grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand." *Williamson v. Consolidated Rail Corp., 926 F.2d 1344, 1352 (3d Cir. 1991).*

III. DISCUSSION

A. Infringement

Under § 271(a) of the Patent Act,

> except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.

35 U.S.C. § 271(a). Determining infringement is a two-step process. First, the court must [*7] construe the asserted claims so as to ascertain their meaning and scope. See *Kahn v. General Motors Corp., 135 F.3d 1472, 1476 (Fed. Cir. 1998).* Here, the parties do not dispute the court's construction of the claims. Second, the claims as construed are compared to the accused device. See id. In order to be found infringing, each and every claim element must be present, either literally or by an equivalent, in the accused device. See *Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 398 (Fed. Cir. 1994).* In the case at bar, plaintiff had the burden of proving at trial, by a preponderance of the evidence, that every claim limitation was met by the accused device. See *Kahn, 135 F.3d at 1476.*

1. Claims 1 and 37 of the *'306* patent

Initially, plaintiff argues that, based upon the jury's verdict and the undisputed evidence of record, it is entitled to JMOL with respect to infringement of claims 1 and 37 of the *'306* patent. The jury found that defendant's DDSC infringes, either literally or by equivalence, claim 73 of the *'291* patent. This claim reads as follows:

> 73. A method for analyzing a material using a differential scanning calorimeter comprising the [*8] steps of:
>
> (a) selecting an underlying heating rate, modulation frequency and modulation amplitude;
>
> (b) placing a sample of the material in the differential scanning calorimeter;
>
> (c) varying the temperature of the sample in the differential scanning calorimeter according to the selected underlying heating rate, the selected modulation frequency and the selected modulation amplitude;
>
> (d) recording a signal representative of differential changes in the heat flow to and from the sample;
>
> (e) storing the differential signal representative of the heat flow as heat flow data, said heat flow data forming a heat flow data set;
>
> (i) separating the dependence of the heat flow data set on temperature into at least one component data set; and
>
> (j) plotting said at least one component data set on an output device.

(D.I. 1, Ex. D at col. 22, lns. 32-52) The jury's finding of infringement is a determination that each and every element of claim 73 is found in defendant's DDSC, either literally or under the doctrine of equivalents. Elements (a) - (d) of claim 73 are identical to elements (a) - (d) of claims 1 and 37 of the *'306* patent. (D.I. 1, Exs. C, D) [*9] Since the jury found these elements to be satisfied by defendant's DDSC when it found infringement of the corresponding elements of claim 73 of the *'291* patent, a consistent interpretation of the jury's verdict n2 requires finding that these elements are satisfied with respect to claims 1 and 37 of the *'306* patent.

> n2 The court is required to adopt a view of the case that is consistent with the jury's verdict. See, e.g., *Anastasio v. Schering Corp., 838 F.2d 701, 710 (3d Cir. 1988)* (holding that the district court was correct in adopting a view of the case

> "under which the jury's answers to the interrogatories are consistent"); *Barnhart v. Dollar Rent a Car Sys., Inc., 595 F.2d 914, 919 (3d Cir. 1979)* (stating that "a court must interpret a jury's findings of fact as consistent whenever possible").

Claim 73 differs from claims 1 and 37 of the *'306* patent only in that claim 73 does not speak of deconvolution. Both claim 1 and 37 of the *'306* conclude with an element (e) that refers to "deconvoluting." Specifically, [*10] claim 1 reads:

> (e) deconvoluting the signal representative of differential changes in the heat flow to and from the sample to compute at least one deconvoluted signal.

(D.I. 1, Ex. C at col. 16, lns. 9-12) Similarly, claim 37 concludes:

> (e) deconvoluting the signal representative of differential changes in the heat flow to and from the sample to compute two deconvoluted signals.

(D.I. 1, Ex. C at col. 20, lns. 51-53) By contrast, elements (e), (i), and (j) of claim 73 of the *'291* patent refer to storing the heat flow data, "separating . . . the heat flow data . . . into at least one component data set," and plotting the component data set "on an output device." (D.I. 1, Ex. D at col. 22, lns. 45-52) Thus, the difference in the jury's infringement findings with respect to claims 1 and 37 of the *'306* patent and claim 73 of the *'291* patent must be attributable to the issue of deconvolution, i.e., it is reasonable to infer that the jury determined that the DDSC did not "deconvolute" as recited in claims 1 and 37 but did "separate . . . into at least one component data set" within the meaning of claim 73 of the *'291* patent. n3

> n3 Defendant argues that claim 73 is broader than claims 1 and 37 because it does not require deconvolution into "two or more component parts" but only separation into "at least one component data set." (D.I. 333 at 7-9) Defendant maintains it is because of this difference in scope that the jury found only claim 73 to be infringed and invalid. Such an analysis, however, begs the question as to whether there exists substantial evidence supporting the jury's finding regarding deconvolution. A finding that there exists substantial evidence that defendant's DDSC deconvolutes is not inconsistent with a determination that claim 73 is broader in scope than claims 1 and 37.

[*11]

The issue before the court, therefore, is whether the jury's finding with respect to whether defendant's DDSC deconvolutes, as that term was defined by the court, is supported by substantial evidence. The court construed the term "deconvolution" to be a

> process of separating the dependence of a characterizing physical parameter on a driving variable into two or more component parts so that the component parts can be utilized or analyzed separately, or compared with each other. For example, the dependence of a characterizing physical parameter can be deconvoluted into rapidly reversible and non-rapidly reversible components. . . . In sum, the claims require that a signal representative of differential changes in the heat flow to and from the sample be separated into two or more component parts, and that the component parts can be identifiable for separate analysis.

(D.I. 328, Ex. 1)

Plaintiff contends that defendant's DDSC deconvolutes as defined by the court. In support of its contention, plaintiff points to the testimony of Dr. Marcel Margulies, defendant's expert witness and a co-inventor of the DDSC, who testified that the DDSC takes the measured heat flow signal [*12] and breaks it down into a DC and an AC component; from this latter component a real and an imaginary (or storage and loss) signal are calculated. (D.I. 311 at 1756-58, 1760)

Plaintiff also looks to the language of U.S. Patent

No. *5,549,387* ("the *'387* patent"), which defendant admits accurately describes the processing used in the DDSC. The abstract of the *'387* patent states that

> the invention is directed to a differential analysis method and apparatus wherein . . . the measured differential signal is processed into real and imaginary components relating, respectively, to the energy storage and energy loss portions of the signal.

(D.I. 308 at 937-39) Dr. Margulies, a co-inventor of the *'387* patent, qualified this language, stating that although the DDSC calculates components of the measured heat flow signal, these signals are completely and totally independent of one another, i.e., they have a different physical significance. (D.I. 308 at 939-40, 1758-59) He explained that these signals are components "in the mathematical sense of the word" but not, in his opinion, as defined by plaintiff's patents. According to Dr. Margulies, the signal described by the patents at [*13] issue is broken into two parts such that the sum of those parts is equal to the input. (D.I. 308 at 939-40, 1758-59) In contrast, "[a] patent examiner with a degree in mathematics, physics, electrical engineering, reading [the *'387* patent] would understand perfectly well that these are components" in the mathematical sense, i.e., the sum of the parts is not equal to the input. (D.I. 308 at 940)

Plaintiff directs the court to the testimony of other Perkin-Elmer employees as well as another co-inventor of the *'387* patent, all of whom testified that the DDSC does deconvolute the heat flow signal into an AC and a DC component, consistent with the court's definition of the term, i.e., "separation of the signal into any two components." (D.I. 307 at 647-49; D.I. 309 at 1035-36; D.I. 310 at 1440-41) Finally, plaintiff looks to the testimony of its own experts, Dr. Richard Lee and Professor Bernhard Wunderlich. According to these witnesses, the DDSC separates the heat flow signal into a DC component and an AC component and then further analyzes the AC component by separating it into two further components, in-phase and out-of-phase with the temperature, the amplitudes of which are called [*14] the real and imaginary (storage and loss) signals. (D.I. 308 at 833; D.I. 313 at 2092-93)

Rather than counter plaintiff's assertion that the component separation aspect of deconvolution is met by the DDSC, n4 defendant argues that deconvolution requires "the application of the temperature program defined by the selected underlying heating rate, modulation frequency and modulation amplitude to the sample in order to produce deconvoluted data." (D.I. 333 at 14) Defendant's argument derives from the court's instructions to the jury regarding selection of the parameters defining the temperature program involved in the asserted patents. Specifically, the court stated that

> the temperature program defined by the selected underlying heating rate, modulation frequency, and modulation amplitude **must be applied to the sample** material in order to produce deconvoluted data.

(D.I. 316 at 2621) (emphasis added). n5 The court's instructions indicated that this "applied to the sample" requirement was applicable to all of the asserted claims. (D.I. 316 at 2620) According to defendant, a logical explanation of the jury's verdict is that, based upon substantial evidence presented [*15] at trial, the jury found the DDSC does not apply a temperature program defined by an underlying heating rate, modulation frequency, and modulation amplitude to the sample in order to produce deconvoluted data.

n4 Defendant concedes that

> **all** of the asserted claims, including claim 73, include the term "components." Thus, evidence relating to the nature of the "components" that are processed by the DDSC accessory could not have been the distinguishing factor resulting in the jury's finding of infringement of claim 73 and no infringement of all other asserted claims.

D.I. 333 at 19-20) (emphasis in original).

n5 Prior to trial, the court had denied the parties' cross-motions for summary judgment on the basis of this very issue, finding that there existed a question of fact as to "whether

> defendant's product, which apparently at some point translates a user-inputted step-wise temperature program into a temperature program having 'an underlying heating rate, modulation frequency and modulation amplitude,' applies the latter modulated temperature program to the subject material in order to produce deconvoluted data." (D.I. 265 at 4)

[*16]

Assuming for purposes of the following analysis that applying a temperature program to heat a sample is part of "deconvolution" and not, as plaintiff argues, a separate element applicable to the "selection" or "input" facet of the invention, n6 there remains the question of whether defendant's argument is consistent with the jury's verdict. Elements (a) through (c) of claim 73 of the *'291* patent speak to the selection of the temperature program parameters and the application of the temperature program to the sample. In finding claim 73 infringed, the jury necessarily found these elements present, either literally or by the doctrine of equivalents, in defendant's DDSC. Thus, the jury found the "applied to the sample" limitation met by the DDSC in connection with claim 73. Since this limitation is recited verbatim in elements (a) through (c) of claims 1 and 37 of the *'306* patent, a consistent interpretation of the jury's verdict requires a determination that the absence of this limitation was not the factor upon which the jury relied to support its finding of noninfringement.

> n6 Alternatively, plaintiff argues that the evidence presented at trial substantially supports a finding that defendant's DDSC does satisfy the "applied to the sample" requirement.

[*17]

Having so found, the court must determine whether the record, without regard to evidence concerning the "applied to the sample" limitation, is sufficient to support the jury's verdict of noninfringement. In order for the accused device to infringe any of the asserted claims, it must deconvolute as that term was construed by the court. As noted above, the record indicates that the DDSC does separate the measured heat flow signal into two components--a DC signal and an AC signal. This latter signal is then further divided into real and imaginary signals. Thus, the DDSC does deconvolute as required by the asserted patents. It is irrelevant to the analysis that these deconvoluted signals cannot be summed to equal the input, as such is not required by the court's construction of the term deconvolution. What is important is that these components are "identifiable for separate analysis." Defendant has not presented, nor has the court's review of the record revealed, any evidence that would support a conclusion that the DDSC does not deconvolute as that term was construed by the court. Although the court is most reluctant to enter judgment contrary to a jury's verdict, it concludes that no [*18] reasonable jury could have found noninfringement with respect to claims 1 and 37 of the *'306* patent on the record created by the parties. Therefore, a verdict contrary to that rendered by the jury is compelled.

2. Claim 17 of the *'775* patent; claims 1, 11, 21 37, and 41 of the *'306* patent; and claim 73 of the *'291* patent

Plaintiff argues that regardless of the jury's verdict the court should enter JMOL on the issue of infringement, both literal and by the doctrine of equivalence, with respect to claim 17 of the *'775* patent; claims 1, 11, 21, 37, and 41 of the *'306* patent; and claim 73 of the *'291* patent because the uncontroverted evidence indicates that defendant's DDSC satisfies the "parameter selection" and "applied to the sample" limitations set forth in the claims at issue. Since the court previously has determined that the jury's verdict is consistent with a finding that these limitations were met by the DDSC, the court need not further address the sufficiency of the evidence in this regard in order to conclude that JMOL should be entered in favor of plaintiff.

B. Obviousness

Under *35 U.S.C. § 103*,

> [a] patent may not be obtained . . . if the differences [*19] between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

In the case at bar, defendant had the burden of proving at trial, by clear and convincing evidence, that (1) all of the

elements of claim 73, with the exception of claim (j), were anticipated by an article entitled "The Measurement of Accurate Heat Capacities by Differential Scanning Calorimetry Comparison of D.S.C. Results on Pyrite (100 to 800 K) with Literature Values from Precision Adiabatic Calorimetry" and authored by S.C. Mraw and D.F. Naas ("the Mraw article") (D.I. 334); and (2) one skilled in the art at the time of the invention would have been motivated to modify the Mraw article to add a "plotter" element. n7 Thus, with respect to elements (a) - (e) and (i), defendant was required to establish at trial that all aspects of these elements are described in the Mraw article. See *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995);* see also *PPG Indus., Inc. v.* [*20] *Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991).*

n7 As a result of pretrial maneuvering, defendant maintained its obviousness defense only as an adjunct to its anticipation defense. At trial, defendant was allowed to add claims 78 and 88 to its obviousness defense only insofar as it was permitted to present evident indicating that the inclusion of a "plotter" element was a "trivial addition." (D.I. 307 at 452-462; D.I. 311 at 1612-20)

Although the ultimate determination of obviousness is a question of law, the decision rests upon factual determinations. See *Richardson-Vicks Inc., 122 F.3d at 1479.* In determining the facts as they may have been found by the jury, the court is required to assess the evidence in the light most favorable to the verdict winner, in this case defendant. See id. However, the court "must not lose sight of the presumption of validity." *Perkin-Elmer Corp., 732 F.2d at* [*21] *893.* Thus, where there is a verdict of invalidity, the question is whether defendant's evidence "so met the burden imposed by *35 U.S.C. § 282* ('the burden of establishing invalidity of a patent or any claim shall rest on the party asserting such invalidity') that reasonable jurors could not have concluded" that defendant did not meet the burden. Id.

Plaintiff argues that the Mraw article neither discloses nor teaches element (i) of claim 73, i.e., "separating the dependence of the heat flow data set on temperature into at least one component data set." However, the proper question on a motion for JMOL is whether there exists substantial evidence in the record to support the jury's finding that element (i) is taught by the Mraw article. The record at bar demonstrates that Dr. Mraw's intent was "to determine how accurately (not just precisely) heat capacities could be measured by [DSC]." (D.I. 334 at B80; D.I. 308 at 795) In order to achieve this result, he measured "the heat capacity of a sample of FeS[2], pyrite . . . from 100 to 300 K by [DSC]." (D.I. 334 at B80; D.I. 308 at 795-96; D.I. 311 at 1749) Dr. Mraw performed two separate runs, each run consisting of 10 to 15 [*22] repeats, and for each run he measured the heat capacity of the pyrite sample. (D.I. 308 at 795-97; D.I. 311 at 1592, 1750-51; D.I. 334 at B81) The heat capacity of the first run was measured using the scanning method n8 and the second using the enthalpy method. n9 (D.I. 308 at 798; D.I. 311 at 1594-96; D.I. 334 at B84-87) Because pyrite does not go through any transitions in the temperature range studied by the Mraw article, the two methods of calculating heat capacity yielded equivalent results. (D.I. 311 at 1597)

n8 The scanning method of calculating heat capacity involved measuring the amplitude of the DSC output signal (i.e., the differential heat flow). In order to calculate heat capacity using the scanning method, Dr. Mraw merely subtracted the baseline value from the DSC output signal. (D.I. 311 at 1595)

n9 The enthalpy method of measuring heat capacity involved integrating the area between the DSC output signal curve and the baseline curve. (D.I. 311 at 1595-96)

In evaluating the Mraw article, Dr. [*23] Margulies testified that "if, by deconvolution, you mean the calculation, the processing of the data to extract very general signals or to extract information, then, yes, it's a deconvolution." (D.I. 311 at 1751-52) In addition, he testified that:

Q: Well, let me ask you this: Is it true that nowhere in the Mraw article is it disclosed that a run is made which generates a heat flow signal, and that heat flow signal, from that single run, is broken down into components. Is that true?

A. No. He subtracts a baseline.

Q. Other than subtracting a baseline, is that true?

A. Other than subtracting a baseline, I think that he uses a single run over 10, 15 steps, how ever many, and uses that information to do the calculation, yes.

Q. So the answer is he doesn't break that signal down into components; correct? Can we just agree on that?

A. He does a calculation.

Q. He does not break the signal down into components; is that correct?

A. I don't know what you call components.

(D.I. 311 at 1753-54) Dr. Lee testified that the Mraw article does not teach deconvolution as that term is "defined in [plaintiff's] patents." (D.I. 308 at 797-98) According [*24] to Dr. Lee, Dr. Mraw merely calculated heat capacity using two different methods of calculation:

Q. So is it fair to say he does one run or experiment and then he goes through and comes up with one heat capacity measurement and then he goes back and runs another experiment using a different formulation, comes up with another heat capacity; is that correct?

A. That's correct.

Q. But does he ever take one set of data and unravel it into separate components . . .?

A. He never satisfied the definition of deconvolution in terms of separating into two components as defined in the patent.

(D.I. 308 at 798)

Claim 73 requires "separating the dependence of the heat flow data set on temperature into at least one component data set." Despite defendant's argument that the Mraw article teaches two ways to deconvolute--the scanning method and the enthalpy method--and sets forth two component data sets--one for the scanning method and one for the enthalpy method--such is not supported by the record. The evidence indicates that the Mraw article describes two methods of calculating heat capacity performed on two separate data sets. There is nothing in the record to support [*25] a conclusion that the calculation of heat capacity from the measured differential heat flow signal constitutes the separation of a single measured heat flow signal into "at least one component data set" as required by claim 73. Dr. Margulies' testimony does not indicate otherwise. At no point in the record does Dr. Margulies either expressly or implicitly indicate that the Mraw article teaches the separation of the heat flow data signal into at least one component data set. Moreover, since pyrite does not go through any transitions in the temperature range studied, the data measured by Dr. Mraw cannot possibly demonstrate the separation of component data in the presence of transitions as required by the asserted patents.

The court concludes that the evidence presented at trial does not constitute clear and convincing proof that claim 73 of the *'291* patent is invalid as obvious. The Mraw article does not disclose element (i) of claim 73, i.e., it does not teach the separation of the heat flow data set "into at least one component data set." Consequently, with respect to this element it cannot be said that "there [is] no difference between the claimed invention and the reference disclosure, [*26] as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found., 927 F.2d at 1576.* Viewing the evidence in a light most favorable to defendant, the court nevertheless concludes that the record is insufficient to support the jury's verdict on obviousness.

IV. CONCLUSION

For the reasons stated above, the court concludes that there is no legally sufficient evidentiary basis for a reasonable jury to have found for defendant on the issues of noninfringement and obviousness. Therefore, plaintiff's renewed motion for JMOL pursuant to *Fed.R.Civ.P. 50(b)* is granted. (D.I. 326) As a result of the finding of infringement, plaintiff is entitled to an injunction preventing defendant from infringing the asserted claims. In the event the court's grant of JMOL in favor of plaintiff is reversed, the court conditionally grants plaintiff's motion for a new trial on the issues of

infringement and obviousness pursuant to *Fed.R.Civ.P. 50(c)(1)* and *59*. Finally, with respect to the issues of willfulness and damages, the court conditionally grants plaintiff's motion for a new trial on the affirmation on appeal of this court's grant of JMOL. Such is warranted [*27] given the court's conclusions regarding the issues of infringement and validity. n10

n10 As defendant correctly points out, the jury did consider the issue of willfulness, finding that defendant's infringement was not willful. Based on the court's instructions, however, the jury should not have answered the willfulness question since it did not find a single claim of plaintiff's to be both infringed and valid. (D.I. 316 at 2615) Since the jury predicated its finding on conclusions concerning infringement and obviousness which conflict with those of the court's, the court concludes that a new trial addressing the issues of damages and willfulness is warranted.

An appropriate order shall issue.

EXHIBIT 5

LEXSEE 2000 US APP LEXIS 12024

Analysis
As of: Sep 25, 2007

TA INSTRUMENTS, INC., Plaintiff-Appellee, v. THE PERKIN-ELMER CORPORATION, Defendant-Appellant.

99-1358

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2000 U.S. App. LEXIS 12024

June 1, 2000, Decided

NOTICE: [*1] RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

SUBSEQUENT HISTORY: Rehearing Denied and Rehearing En Banc Declined July 10, 2000, Reported at: *2000 U.S. App. LEXIS 17778*. Reported in Table Case Format at: *2000 U.S. App. LEXIS 38445*

DISPOSITION: Vacated and remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Defendant appealed from the judgment of the United States District Court for the District of Delaware granting plaintiff judgment as a matter law in plaintiff's action for patent infringement.

OVERVIEW: Plaintiff sued claiming defendant's accused devise, a dynamic differential scanning calorimeter (DDSC), infringed various claims of its three related patents. Defendant counterclaimed, asserting plaintiff's products infringed claim one of defendant's patent. The jury found only one of plaintiff's claims was infringed, under the doctrine of equivalents, but was obvious. The district court granted plaintiff judgment as a matter of law (JMOL) on its other claims, and defendant appealed. The court affirmed JMOL to the extent it held plaintiff's other claims were infringed under the doctrine of equivalents, finding the jury verdict of non-infringement was not supported by substantial evidence. The court affirmed JMOL as to claim validity contrary to the jury finding of obviousness, holding the jury's verdict on obviousness was not supported by substantial evidence, but reversed the conditional grant of a new trial on the issue of willfulness, holding the district court's reliance on the jury's supposed failure to follow its instructions was misplaced because the jury followed the instructions on the special verdict form when it reached the question of willfulness.

OUTCOME: The court affirmed the district court's grant of judgment as a matter law to the extent it found plaintiff's claims were infringed under the doctrine of equivalents and on the issue of validity, but vacated the district court's conditional grant of a new trial on the issue of the willfulness and its judgment that plaintiff had not infringed defendant's patent.

LexisNexis(R) Headnotes

Civil Procedure > Appeals > Reviewability > Preservation for Review
Civil Procedure > Appeals > Standards of Review > Substantial Evidence > Sufficiency of Evidence
[HN1] The sufficiency of the evidence can not be reviewed on appeal after a jury verdict absent some post-verdict disposition, either by a deferred ruling or upon a post-verdict motion.

Civil Procedure > Appeals > Reviewability > Preservation for Review

Civil Procedure > Appeals > Standards of Review > Substantial Evidence > Sufficiency of Evidence
Patent Law > Infringement Actions > Doctrine of Equivalents > Fact & Law Issues
[HN2] The presentation of doctrine of equivalents-type evidence is not a pure issue of law that can be reviewed in the absence of a post-verdict ruling on the sufficiency of the evidence after a jury verdict.

Civil Procedure > Trials > Judgment as Matter of Law > General Overview
Civil Procedure > Appeals > Standards of Review > De Novo Review
Civil Procedure > Appeals > Standards of Review > Substantial Evidence > Sufficiency of Evidence
[HN3] A district court's grant of judgment as a matter law (JMOL) is reviewed de novo, applying the same standard as the district court. A grant of JMOL will be affirmed only if the reviewing court finds that the jury verdict was not supported by substantial evidence.

Patent Law > Infringement Actions > Infringing Acts > General Overview
[HN4] An infringement analysis entails two steps: (1) determining the meaning and scope of the claims and (2) comparing the properly construed claims to the accused device.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence > Sufficiency of Evidence
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN5] Obviousness is a question of law based on underlying factual inquiries, including the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art at issue.

Civil Procedure > Trials > Judgment as Matter of Law > General Overview
Civil Procedure > Judgments > Relief From Judgment > Motions for New Trials
Civil Procedure > Appeals > Standards of Review > Abuse of Discretion
[HN6] The grant of a new trial is reviewed for abuse of discretion. Because *Fed. Rule Civ. P. 50(c)* requires courts to specify the grounds for granting the motion for the new trial, the grant of a new trial is reviewed in light of the grounds set forth by the district court. *Fed. Rule Civ. P. 50(c)* (1998).

Civil Procedure > Appeals > Standards of Review > De Novo Review
Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN7] Claim construction is a question of law that we review de novo.

Civil Procedure > Appeals > Standards of Review > De Novo Review
Patent Law > Infringement Actions > Claim Interpretation > Means Plus Function
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN8] Whether the language of a claim is to be interpreted according to *35 U.S.C.S § 112*, P 6, is a question of law, reviewed de novo.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN9] In accordance with *35 U.S.C.S. § 112*, P 6, a limitation must be construed to cover the corresponding structure described in the specification and equivalents thereof. *35 U.S.C.S. § 112*, P 6.

Criminal Law & Procedure > Defenses > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN10] Infringement of a claim under *35 U.S.C.S. § 112*, P 6 (1994), is a question of fact that an appellate court will not decide in the first instance.

JUDGES: Before MAYER, Chief Judge, SCHALL, and GAJARSA, Circuit Judges.

OPINION BY: SCHALL

OPINION

SCHALL, *Circuit Judge*.

DECISION

The Perkin-Elmer Corporation ("Perkin-Elmer") appeals from the final judgment of the United States District Court for the District of Delaware that granted TA Instruments, Inc.'s ("TA's") motion for judgment as a matter law ("JMOL") that Perkin-Elmer infringed claim 17 of *U.S. Patent No. 5,224,755 ("the '775 patent")*, claims 1, 11, 21, 37 and 41 of *U.S. Patent No. 5,346,306 ("the '306 patent")*, and claim 73 of *U.S. Patent No.*

5,439,291 ("the '291 patent") [1] either literally or under the doctrine of equivalents, and that claim 73 of the *'291 patent* is valid. *See TA Instrs., Inc. v. Perkin-Elmer Corp.*, 99-545 (Apr. 6, 1999) (Final Judgment). Perkin-Elmer also appeals the district court's conditional grant of TA's motion for a new trial on the issues of infringement, obviousness, and willfulness. *See id.* On its counter-claim, Perkin-Elmer appeals the district **[*2]** court's final judgment that TA does not infringe *U.S. Patent No. 4,246,641* ("the Babil patent"). *See id.*

1 These patents are referred to collectively as "the Reading patents."

With respect to the Reading patents, we *affirm* the district court's grant of JMOL to the extent that it held the claims to be infringed under the doctrine of equivalents and held claim 73 to be valid. We *vacate* the district court's grant of a new trial on the issue of willfulness. Because the district court's grant of a new trial on the issues of infringement and obviousness was conditioned on a reversal of the JMOL, we do not address this conditional grant. With respect to the Babil patent, we *vacate* the district court's judgment of noninfringement and *remand* the case to the district court for further proceedings in accordance with this opinion.

DISCUSSION

I.

TA, the assignee of the Reading patents, sued Perkin-Elmer for infringement of claim 17 of the *'755 patent*, claims 1, 11, 21, 26, 37 and 41 of the *'306 patent*, **[*3]** and claims 11, 38, 73 and 88 of the *'291 patent*. [2] Perkin-Elmer, the assignee of the Babil patent, counter-claimed for infringement of claim 1 of the Babil patent. We first address Perkin-Elmer's appeal with respect to the Reading patents.

2 The Reading patents are related as parent (the '775 patent), continuation (the *'306 patent*) and continuation-in-part (the *'291 patent*).

A. *The Reading Patents*

The inventions of the Reading patents are directed to differential analysis. As described in the patents, this technology measures the changes in a physical property (the "characterizing differential physical parameter") of a sample material in response to a change in some physical factor (the "driving variable"), such as temperature, pressure, or applied stress. *See, e.g.*, '775 pat., col. 1, l. 55 - col. 3, l. 11. The resulting data is used to obtain information about the material. Although the patents contain broad language as to the physical property that can be measured and the physical factor that **[*4]** can be changed, the accused device and prior art measure changes in the same physical property--heat flow to and from the sample--in response to changes in the same physical factor--temperature. This type of differential analysis may yield, for example, information about the material's heat capacity. [3] It is referred to as differential scanning calorimetry ("DSC"). In some applications of DSC, the changes in heat flow to and from the sample material are compared to changes in heat flow to and from a reference material, where the reference material is also subject to a change in temperature.

3 A material's heat capacity reflects the quantity of heat required to raise the material's temperature. *See* Webster's Third New Internat'l Dictionary 1046 (1986).

The parties focus on two aspects of the DSC methods claimed in the Reading patents: the way in which the temperature is changed and the way in which the resulting data is processed to obtain information about the material. Conventional DSC methods change the **[*5]** temperature at a constant rate, according to a linear temperature ramp (if temperature is plotted against time, an upwardly sloping line results). In contrast, the DSC methods of the Reading patents add an oscillating heating rate to a linear temperature ramp (if temperature is plotted against time, an upwardly sloping, oscillating curve results). The '775 and *'306 patents* describe their temperature program as "a rapid heating oscillation . . . added to a conventional linear temperature ramp." *Id.* at col. 4, ll. 14-16; '306 pat., col. 4., ll. 18-20. The two patents describe the preferred embodiment as comprising the steps of selecting the underlying heating rate (the linear temperature ramp), selecting the modulation frequency and modulation amplitude (the frequency and period of the oscillating heating rate), and applying a modulation with the selected frequency and amplitude to the underlying heating rate (achieving a temperature program that follows an upwardly sloping, oscillating curve). *See* '775 pat., col. 8, ll. 25-30; '306 pat., col. 8., ll. 25-32. The *'291 patent* describes the preferred heating program as exposing the sample material "to both an oscillating heating **[*6]** rate component and a constant heating rate component." '291 pat., col. 5, ll. 29-31. [4]

4 The *'291 patent* also incorporates the '775 and *'306 patents* by reference. *See* '291 pat., col. 1, ll. 5-11.

The Reading patents teach that the heat flow data can be processed to "deconvolute" the data into two or more components. The *'306 patent* defines deconvolution as follows:

> "Deconvolution", as used herein, means the process of separating the dependence of a characterizing physical parameter

> such as total heat flow on temperature into two or more component parts so that the component parts can be utilized or analyzed separately, or compared with each other. For example, the dependence of the total heat flow can be deconvoluted into rapidly reversible heat flow and non-rapidly reversible heat flow components.

'306 pat., col. 3., ll. 40-47. A similar definition is set forth in the '775 and *'291 patents*. *See* '775 pat., col. 3, ll. 37-44; '291 pat., col. 4, ll. 23-31. The Reading patents exemplify **[*7]** deconvolution as separating the data (i.e., the change in heat flow to and from the sample in response to changes in temperature) into a rapidly reversible component and a non-rapidly reversible component. The rapidly reversible component is dependent on the rate of change of the temperature of the sample material ("the rate of change of the driving variable") whereas the non-rapidly reversible component is dependent on the actual temperature of the sample material ("the value of the driving variable"). See '775 pat., col. 3, ll. 12-36. The '775 patent teaches that this ability to deconvolute data is important when rapidly reversible and non-rapidly reversible events occur at the same or overlapping times, and permits the study of events which occur at the same temperature. *See id.* at col. 5, ll. 15-18. Deconvolution is achieved by applying certain mathematical functions to the heat flow data. *See id.* at col. 4, ll. 26-43.

Claims 1 and 37 of the *'306 patent* are representative of the asserted claims of the Reading patents:

> 1. A method for analyzing a material using a differential scanning calorimeter comprising the steps of:
>
> (a) selecting an underlying heating rate, modulation **[*8]** frequency and modulation amplitude;
>
> (b) placing a sample of the material in the differential scanning calorimeter;
>
> (c) varying the temperature of the sample in the differential scanning calorimeter according to the selected underlying heating rate, the selected modulation frequency and the selected modulation amplitude;
>
> (d) recording a signal representative of differential changes in the heat flow to and from the sample; and
>
> (e) deconvoluting the signal representative of differential changes in the heat flow to and from the sample to compute at least one deconvoluted signal.
>
> 37. A method for analyzing a material using a differential scanning calorimeter comprising the steps of:
>
> (a) selecting an underlying heating rate, modulation frequency and modulation amplitude;
>
> (b) placing a sample of the material in the differential scanning calorimeter;
>
> (c) varying the temperature of the sample in the differential scanning calorimeter according to the selected underlying heating rate, the selected modulation frequency and the selected modulation amplitude;
>
> (d) recording a signal representative of differential changes in the heat flow to and from the sample; and
>
> (e) deconvoluting the **[*9]** signal representative of differential changes in the heat flow to and from the sample to compute two deconvoluted signals.

Claim 73 of the *'291 patent* is the only claim the jury found to be infringed:

> 73. A method for analyzing a material using a differential scanning calorimeter comprising the steps of:
>
> (a) selecting an underlying heating rate, modulation frequency and modulation amplitude;
>
> (b) placing a sample of the material in the differential scanning calorimeter;
>
> (c) varying the temperature of the sample in the differential scanning calorimeter according to the selected underlying heating rate, the selected modulation frequency and the selected modulation amplitude;
>
> (d) recording a signal representative of differential changes in the heat flow to and from the sample;
>
> (e) storing the differential signal representative of the heat flow as heat flow

> data, said heat flow data forming a heat flow data set;
>
> (i) separating the dependence of the heat flow data set on temperature into at least one component data set; and
>
> (j) plotting said at least one component data set on an output device.

B. *The Accused Device*

The accused device is Perkin-Elmer's Dynamic **[*10]** Differential Scanning Calorimeter ("DDSC"). The DDSC uses a temperature program that Perkin-Elmer describes as a sequential combination of a short linear ramp (where the temperature is steadily increasing) and an isotherm (where the temperature is constant). When the temperature of this program is plotted against time, an upwardly sloping, zig-zag line results. In operation, the operator selects a starting temperature ("T1"), an ending temperature ("T2"), and the time ("t") that the device will take to reach T2 from T1 and will remain at T2 before heating to the next temperature. The device uses this information to generate a control signal for the temperature program. The device applies a filter to the control signal to eliminate irregularities. In order to preserve the zig-zag shape of the temperature program, the device separates the control signal for the temperature program into two component signals and applies the filter to only one of the signals. Specifically, the device separates the control signal into a ramp signal, where the ramp represents the average heating rate of the temperature program, and a sawtooth waveform signal, where the sawtooth waveform has the same frequency **[*11]** and amplitude as the zig-zags of the temperature program. The ramp signal is filtered and then combined with the sawtooth waveform signal to generate the zig-zag temperature program. The DDSC produces two signals that can be evaluated and compared.

Perkin-Elmer admits that "elements (b), (d), (e), (i) and (j)" of claim 73 of the *'291 patent* "are clearly present in the use of the accused equipment." Brief for Appellant at 26, n.11. These elements are:

> (b) placing a sample of the material in the differential scanning calorimeter;
>
> (d) recording a signal representative of differential changes in the heat flow to and from the sample;
>
> (e) storing the differential signal representative of the heat flow as heat flow data, said heat flow data forming a heat flow data set;
>
> (i) separating the dependence of the heat flow data set on temperature into at least one component data set; and
>
> (j) plotting said at least one component data set on an output device.

II.

Perkin-Elmer's infringement of the Reading patents was tried to a jury. The district court construed the claims with respect to the selection of the temperature program and with respect to deconvolution. The following claim **[*12]** construction was provided to the jury:

> The selection, means for selection, or preselection of . . . [required] temperature program parameters can be accomplished through any combination of computer hardware, computer software, or operator control. The claims of TA's patents do not require a specific user of equipment to specifically choose the underlying heating rate, modulation frequency, and modulation amplitude. Selection may be accomplished, in whole or in part, through programming of the computer and the equipment. There is nothing in the specification or the claim language which limits the selection process or means for selecting to any particular temporal or physical format. The temperature program defined by the selected underlying heating rate, modulation frequency, and modulation amplitude must be applied to the sample material in order to produce deconvoluted data.

Trial Tr. at 2620-21.

> Claim 17 of the '775 patent, Claims 1, 11, 21, 26, 37 and 41 of the *'306 patent*, and Claims 11 and 38 of the *'291 patent* use the term "deconvoluting." You should understand "deconvoluting" according to its definition in the patents, as set forth in column 3, lines 40 through **[*13]** 47, of the *'306 patent* and column 4, lines 23 through 26, of the *'291 patent*. The same definition is used in each of the patents. That definition is:

> "Deconvolution", as used herein, means the process of separating the dependence of a characterizing physical parameter such as total heat flow on temperature into two or more component parts so that the component parts can be utilized or analyzed separately, or compared with each other. For example, the dependence of the total heat flow can be deconvoluted into rapidly reversible heat flow and non-rapidly reversible heat flow components.

> The driving variable in a DSC instrument is temperature. The term "characterizing physical parameter" is separately defined in the patents in column 3, lines 10 through 14, of the *'306 patent*, and at column 3, lines 58 through 62, of the *'291 patent*.
>
> The same definition is used in both patents. That definition is: "Characterizing differential physical parameter", as used herein, means the dependent differential physical parameter characterizing the sample, such as its heat flow, weight change, or change in dielectric or mechanical properties.
>
> One characterizing differential physical parameter **[*14]** in a DSC instrument is the heat flow to the sample with respect to the reference that characterizes the sample.
>
> In sum, the claims require that a signal representative of differential changes in the heat flow to and from the sample be separated into two or more component parts, and that the component parts can be identifiable for separate analysis.

Trial Tr. at 2621-22.

The jury found that the asserted claims of the *'755* and *'306 patents* were not infringed, either literally or under the doctrine of equivalents. The jury also found that these claims were not invalid for failing to satisfy the best mode requirement, were not anticipated by Mraw, J. Chem. Thermodynamics 11: 567-84 (1979) ("Mraw"), and were not obvious. The jury found that claim 73 of the *'291 patent* was infringed under the doctrine of equivalents, was not invalid for failing to satisfy the best mode requirement, was not anticipated by Mraw, but was obvious. The jury found that Perkin-Elmer's infringement of claim 73 of the *'291 patent* was not willful.

Both parties had moved for directed verdicts before the case was submitted to the jury, but the district court reserved judgment on the motions. *See* Trial **[*15]** Tr. at 1273-74, 2082-83. After the jury reached its verdict, only TA renewed its JMOL. TA's JMOL sought a judgment that Perkin-Elmer infringed claim 17 of the '775 patent and claims 1, 11, 21, 37 and 41 of the *'306 patent*, both literally and under the doctrine of equivalents, that Perkin-Elmer literally infringed claim 73 of the *'291 patent*, and that claim 73 of the *'291 patent* is not invalid as obvious in view of the prior art.

The court granted TA's motion. *See TA Instrs., Inc. v. Perkin-Elmer Corp., 1998 U.S. Dist. LEXIS 19548, 95-545 slip op. at 20 (Dec. 7, 1998)*, (Opinion). The court began with the jury's finding that claim 73 of the *'291 patent* was infringed, stating that it was required to adopt a view of the case that was consistent with the jury verdict. *See id.*, slip op. at 5 & 7 n.2. The court turned first to claims 1 and 37 of the *'306 patent*. *See id.*, slip op. at 5. The court noted that elements (a) - (d) of claim 73 of the *'291 patent* are identical to elements (a) - (d) of claims 1 and 37 of the *'306 patent*. *See id.*, slip op. at 6. The court therefore determined that it had to assume that the accused device meets elements (a) - (d) of claims 1 and 37 of the *'306 patent*. *See id.*, **[*16]** slip op. at 6-7. The court then noted that one difference between claim 73 and the other claims is that claim 73 does not recite "deconvoluting." *See id.*, slip op. at 7. From this observation, the court concluded that the jury's different findings on infringement had to be attributed to "deconvolution." *See id.* The court thus framed the issue before it as whether there was substantial evidence to support the jury's implicit finding that the accused device did not "deconvolute." *See id.*, slip op. at 8.

The court considered the evidence in the light of its construction of the term "deconvolution." Doing so, the court determined that the evidence indicated that the accused device did "deconvolute," that there was no evidence that would support a conclusion that it did not "deconvolute," and that no reasonable jury could have found noninfringement with respect to claims 1 and 37 of the *'306 patent*. *See id.*, slip op. at 13-14. Perkin-Elmer had argued that the court's definition of "deconvolution" required that the modulated temperature program be "applied to the sample," and that the jury must have found that the accused device did not "deconvolute" because it

had found **[*17]** that the accused device did not apply a modulated temperature program to the sample. The court determined that this argument was not consistent with the jury's finding of infringement of claim 73, because claim 73 recites the selection of the parameters of a modulated temperature program and the application of that program to the sample. *See id.*, slip op. at 12. The court therefore determined that the "applied to the sample" language in the jury instructions could not have been the basis of the verdict of noninfringement. *See id.*

The court concluded that the jury's verdict that claim 73 of the *'291 patent* was infringed was consistent with a finding that the limitations of claim 17 of the '775 patent, claims 1, 11, 21, 37 and 41 of the *'306 patent*, and claim 73 of the *'291 patent* were met by the accused device. *See id.*, slip op. at 14. Accordingly, the court granted TA's renewed JMOL as to the infringement of these claims.

The court then turned to the validity of claim 73 in view of the Mraw reference. The court determined that there was no substantial evidence to support the jury's finding that Mraw taught element (i) of claim 73, "separating the dependence of the heat **[*18]** flow data set on temperature into at least one component data set." *See id.*, slip op. at 19-20. The court therefore concluded that the record did not support the verdict of invalidity, and granted TA's JMOL that claim 73 is valid. *See id.*

The court conditionally granted TA's motion for a new trial on the issues of infringement and obviousness if its grant of JMOL were reversed; however, it did not set forth any reasons for this conditional grant. *See id.*, slip op. at 20. The court also granted TA's motion for a new trial on the issues of willfulness and damages, conditioned upon its grant of JMOL being affirmed. The court explained this conditional grant as being "warranted given the court's conclusions regarding the issues of infringement and validity." *See id.* The court recognized that the jury had considered whether claim 73 of the *'291 patent* was willfully infringed, but determined that the jury should not have reached the issue in view of its finding that the claim was invalid. *See id.*, slip op. at 20-21 n.10. The court concluded that because the jury's finding on willfulness was predicated "on conclusions concerning infringement and obviousness which conflict **[*19]** with those of the court[]," a new trial on that issue was warranted. *See id.*

Perkin-Elmer appeals from the district court's grant of TA's JMOL request and from its conditional grants of new trials. We have jurisdiction pursuant to *28 U.S.C. § 1295(a)(1)*.

III.

We note at the outset that Perkin-Elmer is precluded from challenging the jury verdict as to the infringement of claim 73 of the *'291 patent* because it failed to renew its JMOL after the jury returned its verdict. Perkin-Elmer argues that because the district court reserved judgment on its pre-verdict motion and effectively ruled on its motion post-verdict when it granted TA's motion, its pre-verdict motion should be given the same effect as if it had been made post-verdict, citing *Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 20 U.S.P.Q.2D (BNA) 1252 (Fed. Cir. 1991)*. TA responds that *Biodex* stands for the proposition that failure to make a post-verdict motion precludes appellate review of the sufficiency of the evidence supporting a jury verdict. TA argues that, under *Biodex*, Perkin-Elmer's failure to make a post-verdict motion precludes its ability to challenge the jury **[*20]** verdict on appeal.

In *Biodex*, we stated that "[HN1] we cannot review the sufficiency of the evidence after a jury verdict absent some post-verdict disposition, either by a deferred ruling or upon a post-verdict motion." *Id. at 862, 20 U.S.P.Q.2D (BNA) at 1261*. Although the district court deferred ruling on Perkin-Elmer's pre-verdict motion, it never made a post-verdict ruling on the motion. Accordingly, we are precluded from reviewing the sufficiency of the evidence supporting the jury verdict that claim 73 was infringed under the doctrine of equivalents.

Perkin-Elmer tries to avoid this result by arguing that it is challenging the legal sufficiency of the jury verdict, not its factual underpinnings. Specifically, it contends that the issue of infringement under the doctrine of equivalents should not have been presented to the jury because there was a complete lack of proof on that issue. This argument, however, challenges the sufficiency of the evidence, and requires us to review the record for substantial evidence of infringement under the doctrine of equivalents. *See, e.g., Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1188-89, 48 U.S.P.Q.2D (BNA) 1001, 1006-08 (Fed. Cir. 1998)* **[*21]** (addressing the appellant's argument that the evidence of record was legally insufficient proof of infringement under the doctrine of equivalents by determining whether there was substantial evidence to support a jury verdict to that effect). Thus, [HN2] the presentation of doctrine of equivalents-type evidence is not a pure issue of law that can be reviewed in the absence of a post-verdict ruling on Perkin-Elmer's JMOL.

[HN3] We review a district court's grant of JMOL *de novo*, applying the same standard as the district court. *See Markman v. Westview Instrs., Inc., 52 F.3d 967, 975, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995)* (en banc), *aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)*. We will affirm a grant of JMOL only if we find that the jury verdict was not supported by substantial evidence. *See id.*

A. *Infringement*

Perkin-Elmer argues that the district court's grant of JMOL of infringement with respect to claim 17 of the '775 patent and claims 1, 11, 21, 37 and 41 of the *'306 patent* was erroneous because the verdicts as to the infringement of claim 73 of the *'291 patent* and the noninfringement of the claims of the '775 and *'306 patents* **[*22]** can be reconciled. It argues that the jury could have found claim 73 to be infringed and the other claims not to be infringed because claim 73 recites "separating" the data, whereas the other claims recite "deconvoluting" data. Perkin-Elmer argues that the district court's claim construction, set forth in its jury instructions, imposed a requirement on "deconvoluting" that it did not impose on "separating." Specifically, Perkin-Elmer argues that the court's claim construction required that the temperature program defined by the selected underlying heating rate, modulation frequency, and modulation amplitude be applied to the sample in order for deconvolution to be possible. Because this claim construction renders the other claims narrower than claim 73, Perkin-Elmer argues that the jury's verdicts can be reconciled and that, therefore, the grant of TA's JMOL was improper.

TA contends, however, that the district court did not base its grant of JMOL on a determination that the jury's verdicts were inconsistent, but, rather, on its conclusion that the verdict of noninfringement was not supported by substantial evidence. TA urges that the only difference between claim 73 and the other **[*23]** claims is deconvolution. TA argues that the evidence of record demonstrates that the accused device performs deconvolution; accordingly, TA asserts, there is a lack of substantial evidence to support a finding that the accused device does not perform this function. TA responds to Perkin-Elmer's argument that the district court's instruction defining deconvolution imposed an additional requirement on the claims that the jury found not to be infringed. TA asserts that the instruction at issue related to element (c) of the claims, "varying the temperature of the sample in the differential scanning calorimeter according to the selected underlying heating rate, the selected modulation frequency and the selected modulation amplitude," rather than to element (i).

[HN4] An infringement analysis entails two steps: (1) determining the meaning and scope of the claims and (2) comparing the properly construed claims to the accused device. *See Markman, 52 F.3d at 975, 34 U.S.P.Q.2D (BNA) at 1326*. The parties do not appeal the district court's claim construction; accordingly, the only issue before us is whether the accused device falls within the scope of the asserted claims. Because we accept **[*24]** the jury's verdict that claim 73 of the *'291 patent* was infringed under the doctrine of equivalents, our inquiry boils down to whether, given that the accused device falls within the scope of claim 73, there is substantial evidence that the accused device does not fall within the scope of claim 17 of the *'755 patent* or claims 1, 11, 21, 37 and 41 of the *'306 patent*.

Both parties appear to agree that the primary difference between claim 73 and the other claims is that claim 73 recites "separating" the data whereas the other claims recite "deconvoluting" the data. The Reading patents, however, define "deconvolution" as "the process of *separating* the dependence of a characterizing physical parameter on a driving variable into two or more component parts." '775 pat., col. 3., ll. 37-40 (emphasis added). We are not persuaded by Perkin-Elmer's argument that the district court's claim construction imposed a requirement on the claims that recite deconvolution that it did not impose on claim 73. Perkin-Elmer points to no evidence of record that would support a finding that there is a difference between applying a temperature program to a sample, as set forth in the district court's claim **[*25]** construction, and varying the temperature of the sample according to a temperature program, as recited in claim 73. [5] Accordingly, we agree with the district court that, given the jury's verdict that claim 73 is infringed, substantial evidence does not support the jury verdict that the other claims are not infringed. [6] Thus, we affirm the JMOL to the extent it held claim 17 of the *'755 patent* and claims 1, 11, 21, 37 and 41 of the *'306 patent* infringed under the doctrine of equivalents.

5 The lack of evidence on this issue is not surprising because the issue arose from the district court's jury instructions, which came after the close of the evidence.

6 We note that the district court appears to have granted JMOL of infringement "either by the doctrine of equivalents or literally." *TA Instrs., Inc. v. Perkin-Elmer Corp., 1998 U.S. Dist. LEXIS 19548, No. C.A. 95-545 (Dec. 7, 1998)* (Order). In granting JMOL as to literal infringement, the court may have overlooked the fact that the jury found that claim 73 was not literally infringed. No portion of the district court's JMOL opinion addresses literal infringement separately from infringement under the doctrine of equivalents or determines that substantial evidence does not support the jury verdict that claim 73 was not literally infringed. Perkin-Elmer argues that the verdict of no literal infringement is supported by substantial evidence, and TA does not present any arguments to the contrary. Moreover, at oral argument TA agreed that we could uphold the JMOL with respect to infringement under the doctrine of equivalents without finding that the claims were literally infringed. Because Perkin-Elmer's liability is the same whether it infringes the claims literally or

under the doctrine of equivalents, any error the district court made in granting JMOL of literal infringement is harmless. Nevertheless, we affirm the grant of JMOL only with respect to infringement under the doctrine of equivalents.

[*26] B. *Validity*

The jury found that claim 73 of the *'291 patent* was invalid as obvious. The only prior art reference before the jury was Mraw. Mraw was alleged to anticipate steps (a) - (i) of claim 73 and to render obvious step (j). At issue on appeal is whether Mraw teaches step (i), "separating the dependence of the heat flow data set on temperature into at least one component data set."

Mraw discusses the accuracy of DSC in measuring heat capacity. Mraw used a temperature program that consisted of repeating, alternating units of a linear temperature ramp and an isotherm. In such a program, when temperature is plotted against time, an upwardly sloping zig-zag line results. Mraw ran the temperature program on two samples--sapphire and pyrite--and obtained heat flow and heat capacity data for the samples. Mraw obtained this data by two different methods, the scanning method and the enthalpy method. The samples were subjected to the same temperature program under each method; only the collection and treatment of data was different. In the scanning method, the amplitude of the signal produced by the DSC was measured, while in the enthalpy method, the area under the curve defined **[*27]** by the signal and the baseline was measured. Both methods yielded heat capacity data for the samples at the selected temperatures. Mraw concluded that both the scanning method and the enthalpy method resulted in accurate heat capacity data.

Perkin-Elmer argues that Mraw teaches step (i) of claim 73 because it separates the differential heat flow signal in two different ways, the enthalpy method and the scanning method, to produce two component signals, one from the scanning method and one from the enthalpy method. Perkin-Elmer argues that substantial evidence supports the jury verdict of obviousness because Dr. Marguiles, Perkin-Elmer's technical expert, testified at trial that Mraw separated the heat flow signal into components and also testified that any claim broad enough to cover the accused device would be invalid in view of Mraw.

TA asserts that the district court correctly granted JMOL that claim 73 is not obvious in view of Mraw because Mraw does not teach step (i) of claim 73. TA contends that Mraw did not separate its heat flow data into components, but merely used two different methods to measure heat capacity. TA argues that two calculations of heat capacity from measured **[*28]** heat flow signals obtained by two different methods does not constitute the separation of a measured signal into one or more of its components, as recited in claim 73.

[HN5] Obviousness is a question of law based on underlying factual inquiries, including the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art at issue. *See Graham v. John Deere Co., 383 U.S. 1, 16, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)*. We agree with the district court that substantial evidence does not support the finding implicit in the jury verdict that Mraw teaches step (i) of claim 73.

Mraw did not state that it separated data into components. Instead, Mraw merely calculated the heat capacity of sapphire and pyrite by two different methods, the scanning method and the enthalpy method. In both methods, the sample was subjected to the same temperature program and differential heat flow was measured. Thus, the output signal of both methods was differential heat flow. The two methods differed only in how the signal was used to calculate heat capacity. In the scanning method, the amplitude of the signal, relative **[*29]** to the baseline, was used to calculate heat capacity. In the enthalpy method, the area under the curve defined by the signal and the baseline was integrated to calculate heat capacity. The heat flow signal was never separated into components, as recited in step (i) of claim 73 of the *'291 patent*.

The testimony of Dr. Marguiles cited by Perkin-Elmer does not provide substantial evidence that Mraw teaches step (i) of claim 73. Most of the Marguiles testimony related to a reverse doctrine of equivalents analysis, *see Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 14 U.S.P.Q.2D (BNA) 1942 (Fed. Cir. 1990)*, not an obviousness analysis. *See* Trial Tr. 1591. Specifically, Dr. Marguiles testified that if he were to assume that the Reading patents encompassed the accused device, he would conclude that the Reading patents were obvious. *See* Trial Tr. at 1548, 1591-92. This testimony is not substantial evidence that Mraw renders the claims obvious, although it may explain the jury verdict.

Dr. Marguiles' testimony that Mraw's measurement of heat capacity on two different days might be a "deconvolution," Trial Tr. at 1751-52, does not demonstrate that Mraw **[*30]** teaches "deconvolution" as that term is used in the claims. The district court's claim construction did not define the term as broadly as Dr. Marguiles, who testified that "deconvolution" might include "the processing of data to extract very general signals or to extract information." *Compare* Trial Tr. at 2621-22 (setting forth the district court's claim construction with respect to "deconvolution") and Trial Tr. at 1752 (setting forth Dr. Marguiles' understanding of "deconvolution"). Perkin-Elmer also points to Dr. Marguiles' testimony that

if the sample did not undergo a transition during the temperature range tested, the total heat flow measured by Mraw would be the same as the rapidly reversible component calculated in the TA device. *See* Trial Tr. at 1597. This testimony, however, does not indicate that Mraw teaches separating data into one or more components.

Because the record lacks substantial evidence to support the jury verdict that claim 73 of the *'291 patent* is invalid for obviousness, we affirm the district court's grant of JMOL that this claim is valid.

IV.

Perkin-Elmer argues that the district court abused its discretion when it conditionally granted TA's motion **[*31]** for a new trial on the issues of infringement, obviousness, and willfulness. Because the grant of a new trial on the issues of infringement and obviousness was conditioned on a reversal of the JMOL that we affirm, we need not address that ruling. Accordingly, we consider only the district court's conditional grant of a new trial on the issue of willfulness.

The jury found that Perkin-Elmer's infringement of claim 73 of the *'291 patent* was not willful. The district court granted TA's motion for a new trial on this issue for two reasons. The court concluded that the jury had violated its instructions when it reached this issue without first finding that claim 73 was valid. In addition, the court reasoned that the verdict on this issue was predicated on the jury's erroneous conclusions concerning the obviousness of claim 73 and the noninfringement of the other asserted claims. *See TA Instrs., Inc. v. Perkin-Elmer Corp., 1998 U.S. Dist. LEXIS 19548, at *26, 95-545, slip op. at 20-21 n.10 (Dec. 7, 1998).*

[HN6] We review the grant of a new trial for abuse of discretion. *See Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1333, 52 U.S.P.Q.2D (BNA) 1590, 1599 (Fed. Cir. 1999).* Because *Fed. Rule Civ. P.* **[*32]** *50(c)* requires courts to "specify the grounds for granting . . . the motion for the new trial," we review the grant of a new trial in light of the grounds set forth by the district court. *Fed. Rule Civ. P. 50(c)* (1998). We find it instructive that the court did not grant a new trial based on a finding that the verdict of nonwillfulness was against the weight of the evidence, *cf. id., 52 U.S.P.Q.2D (BNA) at 1600* ("When a verdict is against the weight of the evidence a court may grant a new trial."), or on a finding that an error had occurred that made the trial unfair, *cf. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1580, 1 U.S.P.Q.2D (BNA) 1081, 1094 (Fed. Cir. 1986)* (reversing the grant of a new trial where the moving party had failed to show prejudice from the alleged error). Instead, the court relied only on the jury's supposed failure to follow its instructions and the inconsistency between the other jury verdicts and the court's JMOL grants.

Contrary to the district court's conclusion, the jury followed the jury instructions and the instructions on the special verdict form when it reached the issue of willfulness. Although the court did tell **[*33]** the jury that it would be asked to consider the issue of willfulness if it found that "at least one claim . . . has been infringed and has not been proven invalid," Trial Tr. at 2615, this instruction was given in the overview of the court's charge to the jury, and did not clearly tell the jury that it should not reach the issue of willfulness unless it first found a claim to be both infringed and valid. Moreover, the more specific jury instruction did not predicate a finding of willfulness on a finding of validity. This instruction stated:

> If you find . . . that any Perkin-Elmer product infringes at least one of the claims of the TA patents, you must further decide whether or not TA has proved by clear and convincing evidence that Perkin-Elmer's infringement was willful.

Trial Tr. at 2628. The specific jury instructions do not discuss the issue of validity until after this instruction on willfulness. *See* Trial Tr. at 2630-35. The special verdict form also led the jury to address the issue of willfulness before addressing validity. Questions 1 and 2 of the special verdict form were directed to infringement. Question 3 was directed to willfulness:

> If you **[*34]** answered "YES" with respect to any claim in question 1 or question 2, you must answer this question. Otherwise, skip to question 4.
>
> Has TA Instruments proven by clear and convincing evidence that Perkin-Elmer's Infringement of TA's patents was willful?

Questions 4, 5 and 6 were directed to validity (best mode, anticipation, and obviousness, respectively), and no other question was directed to willfulness. Thus, the jury followed the jury instructions given by the district court and the instructions on the special verdict form when it reached the question of willfulness.

TA argues that the jury verdict of nonwillfulness is suspect because it was rendered in the context of a finding of no liability. This argument fails for several reasons. First, the order in which the jury reached the individual verdicts is not apparent from the record. If the jury followed the order of the special verdict form, it would have

decided that Perkin-Elmer's infringement was not willful before it made its decision of invalidity. In that case, the finding of invalidity (and, hence, no liability) would not undermine the finding of nonwillfulness because the issue of willfulness would have been **[*35]** decided first. Perhaps more importantly, if TA was concerned about the soundness of a verdict on willfulness reached in the absence of a finding of both infringement and validity, it should have asked for clearer jury instructions on the issue, and should have challenged the structure of the special verdict form. Because TA apparently did neither, it cannot now challenge the jury verdict based on the order in which the jury may have reached its decision.

The inconsistency between the district court's grant of JMOL and the jury verdict as to the obviousness of claim 73 and the noninfringement of the other claims does not warrant the grant of a new trial on the issue of willfulness. As discussed above, if the jury reached the issues in the order presented on the special verdict form, it would have decided the issue of willfulness before it decided the issue of validity. Accordingly, the verdict of nonwillfulness may not have been influenced by the verdict of invalidity. Moreover, although the jury found only one of the asserted claims to be infringed, the evidence on the issue of willfulness was the same for all of the asserted claims. *See, e.g.*, Trial Tr. at 1391-92, 1467-1501. Because **[*36]** neither the district court nor TA questioned the sufficiency of the evidence supporting the verdict of nonwillfulness or asserted that the verdict was against the weight of the evidence, the district court's grant of a new trial on this issue was an abuse of discretion. We therefore vacate the district court's conditional grant of a new trial on the issue of willfulness.

V.

Perkin-Elmer also appeals the district court's final judgment that TA does not infringe the Babil patent. After the district court construed the claims of the Babil patent, Perkin-Elmer conceded that it could not establish infringement under that claim construction. *See* Trial Tr. at 2349. Accordingly, the issue of TA's infringement of the Babil patent was not submitted to the jury, and the court entered final judgment of noninfringement in favor of TA. *See TA Instrs., Inc. v. Perkin-Elmer Corp.*, 99-545 (Apr. 6, 1999). The only issue before us, therefore, is whether the district court properly construed claim 1 of the Babil patent.

A. *The Babil Patent*

The Babil patent is directed to a device for heating or cooling a sample to a desired temperature. The Babil device ensures that the sample experiences **[*37]** the precise temperature that is selected. *See* Babil pat., col. 1., ll. 38-43. The invention automatically calibrates temperature so that the sample temperature is the same as the selected temperature across a range of temperatures. *See id.*

The specification of the Babil patent describes the calibration process as follows: The device calibrates temperature at three temperatures (the "calibration temperatures") within the temperature range that is going to be used. *See id.* at col. 1, ll. 49-53. For each of the three temperatures, the device is commanded to reach the selected temperature and permitted to stabilize. Then, the device calculates the difference between the sample temperature and the selected temperature, and uses this difference to calculate an adjusted temperature. The device is then commanded to reach the adjusted temperature and is permitted to stabilize. The device calculates the difference between the sample temperature and the original selected temperature, and uses the difference to calculate a new adjusted temperature. This process is repeated until the sample temperature is the same as the selected temperature. The difference between the selected temperature **[*38]** and the adjusted temperature needed to obtain this result (the "correction factor") is stored in a computer memory. *See id.* at col. 1, l. 53 - col. 2, l. 8, col. 3, l. 24 - col. 4, l. 19. The circuitry shown in Figure 1 of the patent performs this calibration process.

According to the specification, after calibration has been completed, the correction factors are used to calculate the temperature which the device must be commanded to reach (the "corrected temperature") in order to ensure that the sample experiences the selected temperature across the range of temperatures that is going to be used. *See id.* at col. 5, ll. 22-25. Thus, the correction factors obtained for the three calibrated temperatures are used to calculate the corrected temperatures for all of the selected temperatures. The parties refer to the process of using the stored correction factors to calculate a corrected temperature for a selected temperature as "interpolation." The device shown in Figure 3 of the Babil patent, which includes the circuitry of Figure 1, a memory, and a processor for performing interpolation, performs this interpolation process.

Claim 1 of the Babil patent, the only claim asserted **[*39]** against TA, recites:

> 1. A thermal analysis system for heating or cooling a test sample to one or more temperatures within a predetermined temperature scale, comprising in combination:
>
> an oven,
>
> a sample disposed in said oven,

> first means providing a signal proportional to the temperature of said sample,
>
> second means providing a signal proportional to the temperature of the oven including heater means for raising the temperature of the oven,
>
> computer means disposed between said first and second means for correcting automatically for discrepancies between oven temperatures and desired sample temperatures.

B. *The Accused Device*

Perkin-Elmer asserted that TA's products having an "isotrack" mode of operation infringe claim 1 of the Babil patent. The isotrack mode is alleged to perform the following steps:

> 1. The oven is commanded to reach the selected temperature.
>
> 2. The system waits until the sample temperature has stabilized, and waits for at least a predetermined time.
>
> 3. The system determines the difference between the sample temperature and the selected temperature (the "error temperature").
>
> 4. The system commands the oven to reach a temperature that is **[*40]** the selected temperature plus the error temperature (the "adjusted temperature").
>
> 5. Steps 2 - 4 are repeated until the sample temperature is the same as the selected temperature.

See Brief for Appellant, at 55-56.

According to Perkin-Elmer, the isotrack mode performs basically the same steps that are performed in the calibration process of the Babil patent, but incorporates the steps into the experimental runs of the accused device. The accused device does not store corrected temperatures or correction factors and does not use interpolation. Instead, the accused device is alleged to perform the above steps during experimental runs, and to repeat them every 30 seconds, to ensure that the sample temperature experiences the selected temperature.

C. *The District Court's Claim Construction*

The claim limitation at issue on appeal is the "computer means" limitation. The parties agreed that this limitation is a means-plus-function clause encompassed by *35 U.S.C. § 112*, P 6. The district court noted that the function recited in this limitation is "correcting automatically for discrepancies between oven temperatures and desired sample temperatures. **[*41]** " Trial Tr. at 2346. The court determined that the description in the Babil patent of the structure that performs this function "includes the calibration, the correction, and the memory means, all within the computer means." Trial Tr. at 2346. The court therefore construed this claim limitation as "including the function of interpolation." Trial Tr. at 2347-48.

Perkin-Elmer contends that the "computer means" limitation must be construed by determining what structure disclosed in the Babil patent performs the function of "correcting automatically for discrepancies between oven temperatures and desired sample temperatures." Perkin-Elmer argues that this function is performed by the circuitry shown in Figure 1 of the Babil patent, or by a microprocessor implementing this circuit. It further argues that the district court improperly construed the "computer means" limitation by adding an interpolation function to the limitation. Perkin-Elmer asserts that claims 2 and 3 of the Babil patent, which recite calibration and interpolation, demonstrate through the doctrine of claim differentiation that the "computer means" of claim 1 is not required to perform these steps.

TA responds to these **[*42]** arguments by asserting that the Babil patent uses the phrase "correcting automatically for discrepancies between oven temperatures and desired sample temperatures" to refer to the process of determining the correction factor for a given temperature by applying the interpolation function to the correction factors of the calibrated temperatures. Thus, TA argues, the district court correctly construed the "correcting automatically" function as requiring calibration, correction and memory, and as including interpolation. TA asserts that the structure disclosed in the Babil patent that corresponds to the "computer means for correcting automatically . . ." is the device of Figure 3, which includes the circuitry of Figure 1, a memory device, and a processor that performs the interpolation routine.

[HN7] Claim construction is a question of law that we review *de novo*. *See Markman, 52 F.3d at 979, 34 U.S.P.Q.2D (BNA) at 1329*. As a preliminary matter, we agree with the parties and the district court that the "computer means" limitation is encompassed by *35 U.S.C. § 112*, P 6. *See Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1360, 54 U.S.P.Q.2D (BNA) 1308, 1312* **[*43]** ("[HN8] Whether the language of a claim is to be interpreted according to *35 U.S.C. § 112*, P 6, . . . is . . . a question of law, reviewed de novo."). [HN9] In accor-

dance with that statute, the limitation must be "construed to cover the corresponding structure . . . described in the specification and equivalents thereof." *35 U.S.C. § 112*, P 6 (1994). We therefore must determine what structures described in the specification of the Babil patent perform the function of "correcting automatically for discrepancies between oven temperatures and desired sample temperatures."

The specification of the Babil patent describes two structures that perform this function. The first structure is the "automatic calibration means" shown in Figure 1. As described in the Babil patent, this structure cycles the device through the steps of commanding the oven to reach a selected temperature, permitting the sample temperature to stabilize, and comparing the sample temperature to the selected temperature, etc., until the sample temperature reaches the selected temperature. *See* Babil pat., col. 3, ll. 40-47, col. 3, l. 56 - col. 4, l. 5. This structure "corrects automatically **[*44]** for discrepancies between oven temperatures and desired sample temperatures" by adjusting the temperature the oven is commanded to reach until the sample experiences the selected temperature.

The second structure that performs the recited function is the structure shown in Figure 3, which automatically calculates a corrected temperature for each selected temperature. This structure includes the automatic calibration system of Figure 1, the memory 36 of Figure 1, and a processor that applies the interpolation function to determine the corrected temperature corresponding to each selected temperature. *See id.* at col. 5, l. 36 - col. 6, l. 13. This structure calibrates the device at the calibration temperatures, stores the correction factors for each calibrated temperature, interpolates a corrected temperature for each selected temperature, and commands the oven to reach the corrected temperature corresponding to the selected temperature. *See id.* at col. 6, ll. 1-13. This structure "corrects automatically for discrepancies between oven temperatures and desired sample temperatures" by calculating a corrected temperature corresponding to the selected temperature and commanding the **[*45]** oven to reach the corrected temperature so that the sample experiences the selected temperature.

Although the district court was reluctant to construe claim 1 as encompassing both the type of automatic correction performed by the automatic calibration system of Figure 1 and the type of automatic correction performed by the automatic calculation system of Figure 3, *see* Trial Tr. at 2346-47, claim 1 itself supports such a broad construction. The function recited in the claim is "correcting automatically," and there is no limit on how this function is performed. The specification describes two structures that perform this function, the structure of Figure 1, which corrects automatically without interpolation, and the structure of Figure 3, which corrects automatically using interpolation. Both of these structures are corresponding structures for the recited "computer means . . ." under *35 U.S.C. § 112*, P 6. *See Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1357, 51 U.S.P.Q.2D (BNA) 1415, 1422 (Fed. Cir. 1999)* (noting that it is the recited "function alone that serves as the touchstone for identifying the disclosed, corresponding **[*46]** structure").

Because the district court's judgment of noninfringement of the Babil patent was based on an erroneous claim construction, we vacate that judgment and remand for further proceedings consistent with this opinion. [7]

> 7 In so doing, we reject Perkin-Elmer's argument that we can reverse the judgment of noninfringement based on the proffer Perkin-Elmer made as to the accused device. Even if there is no dispute as to the operation of the accused device, [HN10] infringement of a claim under *section 112*, paragraph 6, is a question of fact, *see Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1268, 51 U.S.P.Q.2D (BNA) 1225, 1230 (Fed. Cir. 1999)*, that we will not decide in the first instance. Moreover, as TA emphasizes, TA has not had an opportunity to present any evidence on any defenses to Perkin-Elmer's infringement counter-claim. Accordingly, a reversal would not be appropriate on the present record.

VI

For the foregoing reasons, we *affirm* the district court's grant of TA's JMOL to the extent **[*47]** that the court held that Perkin-Elmer infringed claim 17 of the *'755 patent* and claims 1, 11, 21, 37 and 41 of the *'306 patent* under the doctrine of equivalents. We also *affirm* the district court's grant of TA's JMOL that claim 73 of the '291 is valid. However, we *vacate* the district court's conditional grant of a new trial on the issue of the willfulness of Perkin-Elmer's infringement of the Reading patents. Finally, we *vacate* the district court's judgment that TA does not infringe claim 1 of the Babil patent, and *remand* the case to the district court for further proceedings consistent with this opinion.

Each party shall bear its own costs.

EXHIBIT 6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 143-290
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY TWO
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 7, 2007 9:02 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
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have an improvement in the market.
Q. Were there particular suture properties that you looked at in your work at this time?
A. So, suture strength is just very, very important. If the suture breaks, it can be a patient's safety issue, they could have bleeding or might have to go back in for a second procedure, so strength, knot strength is especially as well as not securing. Sometimes a suture doesn't have to break, it just loosens up again and you still could have serious patient issues, so they are very large considerations, then all of this ease of use or handleability for the surgeon. Again, if you're deep in the body, you're trying to tie knots and get secure knots, things like how smooth it is, how pliable, how many times do you have -- how many throws you have to make before it's secure, even how small the knot is is sometimes important.
Q. In your work did you consider any of these properties more important than others?
A. Strength, strength is a must-have. After that there's more nice-to-haves.
Q. Can you tell the jury whether you considered or looked at the smoothness of a braided suture?
A. Yes, smoothness was one of the considerations we always took into account. We had several ways that we could affect the smoothness through braid construction and processing.

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Q. What were some of the ways that you used to try to affect the smoothness of the braided suture?
A. Far and away the most important process we would use is something called heat stretching where we would just take the braid and pull on it with some heat being applied, and this took the fibers to kind of go over and under in a weave and straighten them out.
THE COURT: Now it's hard to hear you.
A. Yes, I'm sorry, just took the fibers and make this unserated over and under pattern in the braid and straightens them out and condenses and it smooths out the braid.
Q. Were you aware of any use of coatings to try to smooth the surfaces of a braided suture?
A. Coatings we used for standard for slipperiness but not really to smooth out the surfaces. There was some previous attempts in patents where people tried to add coating to smooth out, but it quickly stiffened the braid and made it less pliable, kind of glued all fibers together kind of like a starched shirt, stiff.
Q. What was it about those particular coatings that glued the coatings?
A. Right. So, in part it was how much you put on, if you put too much coating on, it prevents the fibers from being able to move and flex.

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Q. So, when you worked with coatings, how much coating did you generally put on sutures?
A. Well, Mr. Hunter really was one of our coatings specialists, and he figured out if you just put a minute amount of coating, it would literally be under an electron microscopic, you can see the amount just to give you a little bit of slipperiness, kind of a soapy waxing.
Q. Getting back to your work on your patent, what did you do to try and improve the suture? That was your goal?
A. Right. So back in the '80's, there was and from our previous jobs, I mentioned earlier, there was a lot of work on composites, blending different materials together. Composites, just a fancy word for blend to try to get the best properties. I think we mentioned everything from airplane wings to dental composites to golf clubs, and all of those, you know, have to do with combining materials. We thought we could do the same type of approach, combine two materials together in the right way to get the benefits of both and achieve in this case strength and pliability and knot security.
Q. So, how did you go about preparing a suture pursuant to that idea?
A. So first you need to pick some materials that we thought were dissimilar and had the properties of two sets of properties that we're looking for, one being kind of

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slippery, the other in this case for this example being more strong, and then we had made out several different approaches to put those together so that we could maximize their interaction between the two kinds of fibers.
Q. Can you tell the jury a little bit, explain the concept of fiber-to-fiber friction in connection with your invention?
A. Yes, so everyone knows about strength and support for sutures to be strong, but the stronger you make these materials, stiffness and strength kind of go hand-in-hand so you make them strong, but then they get stiff, so what we looked at was we thought no one had really looked at the role of friction and the very microscopic level between the fibers, and that's why we chose this construction where we had one fiber that was very slippery, very lubricious and another that offered another property and put together --
THE COURT: Let me ask you, do you use slippery and lubricious as meaning the same thing?
THE WITNESS: Yes.
Q. So, what was your purpose in incorporating the slippery material, and how did that relate to the friction of the fibers?
A. Right, so if you -- the fibers, the worst case is if you stick all the fibers together, then you no longer have what you think is a textile that can bend and conform, tie knots

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very easily, you have something very stiff like a wire, so the opposite of that would be to have no friction between them so that they could easily slide, and that's what we try to do. We try to put this internal lubricant within the structure with the slippery fibers so that the fibers could bend more easily essentially.
Q. So if the fibers could bend more easily, if you used a slippery material, why didn't you make a suture out of all slippery material?
A. So that was tried, that would make sense. The problem with that is that you have to be able to tie a knot that stays, that's secure. I mentioned earlier that if the knot slips, then the wound can open and you can have serious problems so what we found with the various slippery materials, both the teflon that we had talked about, TPF, we talked about and PE, polyethylene that's FiberWire was that if you made a knot out of them, they would just slip so you just needed to make lubricious have its own properties.
Q. Can you explain what the term "mechanical blend" means?
A. Okay. So mechanical blend in the claims, the constituent elements, the mechanical blend, if you start off with two different fibers, let's say polyethylene and teflon fiber, and if you look at it microscopically, you can still see the polyester fiber and the teflon fibers are separate,

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intact individual fibers. They haven't been melted and formed together, they haven't been combined in a molecular model together, they're still just mechanically together and connected.
Q. How does that term relate if at all to the work that lead to the '446 patent?
A. So the mechanical factor is very important to the lubricity aspect and the pliability piece we're talking about. If you stick -- if you have a chemical blend where you stick it together, you lose that benefit so it's important that we just had this mechanical blend.
Q. Dr. Steckel, in the binder in front of you, could you look at the tab for Exhibit 520, please. Do you recognize that document?
A. Yes, this is my laboratory notebook from 1988.
MS. ELDERKIN: I move into admission Exhibit 520.
THE COURT: All right, fine.
(Laboratory notebook of Dr. Steckel was marked and admitted into evidence as Plaintiff's Exhibit No. 520.)
Q. I'd like to refer you to a page in your notebook that has the last production numbers 2617.
A. Yes.
Q. Those numbers are sort of on an angle on the right-hand side. Do you recognize this page?
A. Yes, this was actually the first time we captured this

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idea and formed the invention of combining these different types of materials into a suture.
Q. Okay. I'm going to ask Mr. Ficocello to highlight that top paragraph on the page, and if you could explain to the jury what you said there in your notebook.
A. Yes, exactly. So the notebook, of course, was where we captured all of our experiments and all of our ideas as a formal way we did that, and what I'm saying here in the background section, this was our preliminary, first evaluation of this new braided sutures where we combined the two different fiber types to get the kind of a 1 plus 1 equals 3 plus deal, and I speak of the different. We initially tried three different combinations in an exploratory way to see which one would give us the best results.
Q. What do those letters, PTE and PTFE mean?
A. That's what poly chemists use. That's the shorthand. PET is more commonly known polyester. PTFE is polycholorofluoroethylene polymers. Most people know it by Dupont, teflon. PP again is the same, polyester, polypropylene, and then the last group were these absorbable or dissolvable sutures, they're special polymers, polyglycolic, and Vicryl, which is a trade name.
Q. Did you actually make braids from PET and PTFE?
A. Perfluorinated polymer. So we were especially grateful

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for PTFE, and the why, again, our objective making something that was strong but felt like silk and handleable. We achieved that.
Q. And did you find anything else with that braid?
A. We did have a surprising result which was even one particular property, which is not tiedown, and probably I should explain what that is.
Q. Please do.
A. When the cardiologist or the orthopedic surgeon is tieing those knots, and they really tie a lot of knots in a row, they form a loop and then slide the knot and maybe three or four knot throws per knot and maybe 50 knots in a certain procedure, so it's that friction knot tiedown is how smooth is that process, if you have to like jerk it down and really pull down, that's a problem. From ease of use from the surgeon's view point, that's a good thing. We found even without a coating, which is standard for all these products, we were able to get knot tiedown even better than silk.
Q. Sir, did there come a time when you filed the patent application to cover this work?
A. Yes. So the process of we submitted the invention to our review board, and we thought it had commercial value and we filed a patent.
Q. Other than this patent, did you have any involvement in

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your career at Depuy Mitek or Ethicon about decisions about filing patents?
A. Yes. I have about 10 patents, and I have managed teams where patents are generated, and as always, it's a means for us to protect the investment we made in research.
Q. Okay. Let's focus your patent again, and that's Exhibit 130. Can you briefly summarize for the jury the invention that you disclosed in your patent.
A. Yes, the invention is again this mechanical blend of two different types of fibers in order to improve pliability, this term that we call handling but maintaining strength.
Q. Do you know why Ethicon never made a suture according to your patent?
A. Oh, yeah, it just wasn't commercially feasible at the time.
Q. Why is that?
A. So this was the early '90's, and some of these, almost all of these fibers, the big companies like Dupont and ICI and some of the other companies had become very worried about litigation from their materials being used in implants, so even though the PTFE that we used in our experiments, Dupont had already told us we would not be able to use that in a commercial suture.
Q. Okay. I'd like just to refer a few parts in your patent. Refer to column 2, lines 58 to 62 and I'll also ask

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Mr. Ficocello to blow that up on the screen and in particular the sentence that starts, "In fact." Maybe you could just read that sentence.
A. Yes, so, "In fact -- "
THE COURT: Wait a second, do you all have your patents with you? Maybe it's useful to see where he's flagging on the patents so you can have that back in the jury room and maybe mark it. Which column are we in?
MS. ELDERKIN: Column 2, the first full page of writing in the patent. No. 2 at the top and then there are line numbers on the side. This is lines 58 to 62.
THE COURT: You'll see it starts, "In fact," I have found unless you do it, you'll forget. Put a star next to it, when either side flags a side, so both sides, you'll have what everybody says. Go ahead.
Q. Okay. Dr. Steckel, maybe you could read that sentence and if you could explain to the jury in your own words.
A. Sure. So, "In fact it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used as well as adjusting the specific configuration of the braid." So we could develop braids that had properties that didn't exist before by choosing two different fiber types, controlling how much we put in, there's a 50-50, 75-25, 40-60 and how we put them together.

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It's important how we put them together. You can end with the best of both worlds, you can end up with the worst of both worlds, so construction turned out to be critical.
Q. Your patent said sutures can have a core. Can you explain what that means?
A. So these braids are actually tubular structure if you think about it. As the braids get larger, they would tend to flatten out like a tape if you didn't put something in the middle, so it would be common to put additional strands in the middle, and that would also add strength to the suture.
Q. So could you in terms of your invention where you used two different kinds of materials, could you make a suture where you have one in the material in the core and the other material braided around that?
A. That was actually some of the early work. Al Hummer had found some of that work, and what he found was he actually got the worst of both worlds, it wasn't any stronger and it wasn't any more pliable, so that's what led us to the thought that to get the benefits of both, you really need to have them interlaced or intertwined so that there was intimate connect during the bending and movement of the braid.
Q. The intertwining kind of two different types?
A. Two different types, right. If they're just sitting

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next to each other, they don't do anything.
Q. Okay. I'd like to refer you to another spot in your patent. It's at the bottom of column 5, you start around line 60. There's some reference here to other treatment of the braid. I wonder if you could explain to the jury what that means. Wait until we get it up on the screen. We ran over to line 1 on column 6. Could you explain what this paragraph is saying?
A. Yes. So the heterogeneous braid. Heterogeneous, again, a fancy word for more than one material. So the composite braid after you prepare it after it comes off the braiding machine, then there's some secondary steps, first you wash it and scour it, and then you go through this heat treating process, heat stretching process, excuse me.
The strands are actually very loose if you think about it on the braiding machine, they're just taut enough to stay together while doing that dance that happens during braiding. When it comes off, it's a little bit rough and a loose braid. You have to densify that, you have to really pull on it with heat so you condense it down into a tight, strong filaments, that's what that paragraph is referring to. After we made the braid, we went through other operations to smooth it out essentially.
THE COURT: What does annealed mean?
THE WITNESS: Annealed is just another temperature

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process, thermal process that's used to describe softening the fibers.
THE COURT: And "in divo" means in the body?
THE WITNESS: Yes.
THE COURT: Just when we flag these, don't forget I'm asking these questions on the assumption not everybody understands these terms, but you have a right to write it down on a piece of paper, and I'll hand it to the witness, okay.
Q. Dr. Steckel, in your experience, to what extent did heat stretching as you reference here at the bottom of column 5 affect certain braid properties?
A. Certainly it has a profound effect on diameter, made smaller and the smoothness, tighten down the braid, and, again, those peaks and valleys of the fibers, even though it's a very, very small microscopic still, and when we stretch it and pull on it, we all know that that smooths out the braid.
Q. Okay. I'd like to refer you to now column 6, lines 5 to 17 of your patent.
A. Yes.
Q. And I'd like to basically take this sentence by sentence because this is the discussion of coating. So if you could read the first sentence here from lines 5 to 8 and then explain to the jury in your own words what that means?

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A. Okay. So, if desired, the surface of the heterogeneous multifilament braid can be coated with a bio-absorbable or non-absorbable coating to further improve the handleability and knot tiedown performance of the braid. So what that means is, again, these composite braids are made up of multi-filaments, very standard practice to put any multifilament braid with one of these coatings depending on which fibers you start off with, we start off with fibers like polyester, start off with non-absorbable, but long story short, if you want to, you could put the composite braid with a coating to further improve those properties. It's a very standard practice.
Q. So it's optional?
A. It's optional. I don't if you'd have a patent if you didn't do it because 95 percent of the coatings are that way.
MR. TAMBURO: Objection.
THE COURT: Overruled.
Q. Now, you referred to the surfaces of the braid being coated. Why the surfaces?
A. Again, it's for this knot tiedown property, and it's sort of like putting soap on the bottom of your drawers of your dresser, a little bit where the two meet so when you're doing a suture tiedown, all you need is a little bit on the surfaces, and it makes a huge effect in how smooth it is

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when you're going through that knot process.
Q. Is there any reason why you don't want it to be more than on the surfaces?
A. Yes. Again, some of the previous art in the literature, if you put too much on, you kind of gunk up the fibers, and you make the braid less pliable again.
Q. Let's look at the sentence that starts, "Most preferably" that starts on line 11 and goes to lines 12 and 13.
A. Right.
Q. Could you explain that?
A. So that's a good follow-up from the point I just made. Again, if there are bad coatings out there, clearly if you put too much on, you can cause the fibers to all stick and bundle together, then you get a stiff braid again.
Q. And then the last sentence in that paragraph, could you read that and explain to the jury what that means?
A. Yeah. So, again, we have some of these fibers are slippery, and if you have enough of them in the braid, then it's possible that a conventional coating, you might not need it so you can envision some cases where that was, could be a benefit.
Q. And, Dr. Steckel, there was some references elsewhere in your patent in the background section.
THE COURT: Just so that when you say to possess a

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significant fractions portion, right --
THE WITNESS: Yes.
THE COURT: -- of the slippery yarn system, that's what you're trying to say there, right?
THE WITNESS: Yes.
Q. So you have some references to coatings, a few references to coatings in the background section of the patent, for example, maybe we should go there, if we can. Column 2, lines 13.
THE COURT: Let's get it. Wait until people flip to it.
Q. Column 2, lines 11 to 13. Maybe if you could read that and explain what you were saying there.
A. Yeah, actually I need to read the sentence before for context.
Q. Sure. How many lines do you want to put up?
A. Right. So, again, this speaks to other ways of trying to get at a strong but pliable suture, and this particular previous patent application, they tried to either melt or put a heavy coating, a line of materials on the second, and that embodiment suffered from the same deficiencies in the sense it was too stiff as the other stiff already available sutures.
Q. Isn't this saying the coatings were bad for multifilament sutures?

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polyethylene.
THE WITNESS: The more you stretch it, the stronger it gets. Ultra high molecular weight polyethylene, it's stretched a lot.
Q. Thank you, Dr. Steckel. You understand that FiberWire is made of a combination of this ultra high molecular weight polyethylene you just described and PET, right?
A. It is again polyester like the bottles, pepsi bottles, those are polyester, PET.
THE COURT: The different plastics?
THE WITNESS: Different plastics.
MR. TAMBURO: It's all plastic.
THE COURT: Like that show, The Graduate?
THE WITNESS: I was paying attention when I saw that movie.
THE COURT: Different kinds of plastic threads, right?
THE WITNESS: Exactly.
THE COURT: All right.
Q. But the particular types of plastic are important. Dr. Steckel just to back up a bit, thank you for the explanation. It's your understanding, Dr. Steckel, that FiberWire, the accused product is made of a combination of this ultra high, ultra strong molecular weight polyethylene?
A. Yes.

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Q. Combined with PT which is polyester, right?
A. Yes.
Q. And I think you said that you did not test a combination of those materials in this development, right?
A. Correct. Our hypothesis was if we could demonstrate the concept with these two materials, it would work for other similar materials.
Q. But you never tested, right?
A. No, we didn't test the whole range of materials, no.
Q. Dr. Steckel, isn't it your understanding that suture passage or passing, I'm sorry, tissue passage or passing suture through tissue -- let me start over. Isn't it your understanding, Dr. Steckel, that passing suture through tissue in tieing knots is all part of suture handleability?
A. Yes, suture handleability a Webster's dictionary definition of handleability, it's a term that we kind of use internally at Ethicon to communicate all these ease of use, so anything you did could exist really as strength fell into that handleability, so I would say yes.
THE COURT: So what is handleability?
THE WITNESS: Other than strength, everything with the surgeon, and, again, if it's too stringy, and he's going to make a knot, if the knot is not securing, he has to make extra throws every time to get security, those are all

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things that go into the ease of use in the surgeon's hands. Those are all, again, it's kind of a delicate term, "handleability," but it doesn't have any scientific meaning.
Q. But it's your understanding that tissue passage and knot tieing are part of handleability?
A. Yes, anything about how the surgeon perceives the suture during his use of it.
Q. Thank you. And it's also your understanding that when passing a suture that's not smooth, you are passing that suture through tissue, you can have an effect called chatter?
A. Yes.
Q. Can you describe chatter for the jury?
A. Yeah, the simple way we used to test it, it's really kind of funny, we take a Styrofoam cup and you put the suture through the hole in the cup, and if you were hear to hear tick-tick-tick.
Q. So it's a ticking sound?
A. Yes.
Q. Or in effect you may not hear it?
A. Yes, exactly, but, again, if you do it every day and you're passing suture through tissue, you may feel that and its smoothness and coating, et cetera.
Q. And if you have a rough suture, isn't it your

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understanding or isn't your understanding that when you're passing it through tissue, when you have a rough suture, you may not be able to make a small radius incision as you might otherwise be able to make?
A. A small radius incision?
Q. Yes, sir.
A. I don't believe that makes sense. I'm not sure what you're asking.
Q. Let me rephrase it. Is it your understanding that if you have a rough suture, a rough suture that has this chatter effect that you just described that you may not be able to make as small an incision as you would otherwise be able to make as if the suture was smooth; is that your understanding?
A. Well, the incision, I believe what you're referring to is the hole that the needle creates which is larger than the suture to begin with, so I can't agree with your statement, but I think I understand what you're asking in terms of chatter and roughness.
Q. You're saying you cannot agree?
A. I cannot agree about the incision, you're not making an incision, you're just passing a needle through.
Q. You were deposed in this case, Dr. Steckel?
A. Yes, sir.
MR. TAMBURO: Your Honor, may I approach the

EXHIBIT 7

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS
	)	Pages 143-290
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY TWO
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 7, 2007 9:02 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

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THE COURT: At some point it was mentioned.
MR. SABER: That's if the PE issue had gone the other way.
THE COURT: It must not have come out in the proposed jury instructions. I want to make sure. I'm going to get you a draft, just a first cut-through.
MS. ELDERKIN: Thank you, your Honor.
(A recess was taken.)

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(Resumed, 11:40 a.m.)
THE COURT: Let me just say while you're here, we handed out a draft of the jury instructions, which is by no means a finished product. I pruned it way down. I'm actually now thinking I could prune it down even further, but you look at it and see if it matches where the case is now, because when you all drafted those instructions, it was way before a bunch of these issues were stipulated to, so --
(Jury enters the courtroom.)
MR. BONELLA: May I continue, your Honor?
THE COURT: Yes, with Dr. Brookstein.
MR. BONELLA: Thank you.
BY MR. BONELLA:
Q. Dr. Brookstein, we were just talking about FiberWire's braiding process at Pearsalls. Did you have a chance when you were at Pearsalls to observe their coating, heating, and stretching processes?
A. Yes, I did.
Q. Did you prepare a demonstrative exhibit to help explain that to the jury?
A. Yes, I did.
MR. BONELLA: Your Honor, I'd like permission to publish Exhibit 622. It's a demonstrative and have Dr. Brookstein step down from the witness stand and come over and help explain it to the jury.

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THE COURT: Yes.
MR. BONELLA: And invite counsel to position themselves however they would like and their expert witness to see as well.
(Witness in front of the jury box.)
THE COURT: By the way, this is Dr. Mukherjee, right?
MR. SABER: Yes.
THE COURT: Who will be defense expert, so he has the right to be here. And, you know, experts from both sides may disagree on certain points, so that's why he's watching this testimony.
MR. BONELLA: Can everyone see?
Q. Dr. Brookstein, is this demonstrative representative of the Pearsalls coating, heating, and stretching processes?
A. Yes, it is.
Q. Okay, I'd like you to start and just go through this real slow. If we could start over here on this side and just explain to the jury what is represented here.
A. Can I start over there?
Q. Right, sure, feel free to come over here.
A. So we have this braiding process, and after we braid, we then -- we dye also, and then after we take the braided dyed suture, we then have to apply a coating to it. So what we do is, we have a frame here, which is sometimes called a creel.

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And we have bobbins of the braided, uncoated, unheated, unstretched suture. And we go through this bath here. It's a dip bath that has a solution of a polymer that becomes the coating polymer, Nusil 2174, that's dissolved in a solvent, like you would dissolve sugar and water. So it goes through this bath here --
Q. Just slow down. So the solution you refer to of the Nusil Med 2174 and the Xylene, what is the Nusil Med 2174?
A. The Nusil Med 2174 is the material that becomes the surface coating on the FiberWire braid.
Q. Okay. And what is the Xylene, and what is its purpose?
A. The Xylene is what we call a solvent which dissolves the Nusil polymer to help it go onto the surface of the braid.
Q. Now, the Xylene, does that end up on the FiberWire product when it's all finished?
A. No. It evaporates off the FiberWire.
Q. So out of this bath, what remains on the FiberWire product?
A. When it comes out of the bath, it has the solution of the polymer Nusil and the Xylene when it comes out of the bath.
Q. When it finishes this whole process, what is left on the suture out of the Nusil Med 2174 and Xylene?
A. Just the Nusil polymer.
Q. Just the Nusil Med 2174?

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A. Yes, sir.
Q. Okay. So the suture that goes into the bath -- and you have three lines represented here?
A. Yes.
Q. What do those three lines represent?
A. These would be a depiction of the various sutures. I don't know, I think they might have had eight or ten, but we just to make it easy just did three. So each one of these is an uncoated, unstretched, unheated suture.
Q. So is the process doing multiple sutures at the same time?
A. Yes. It's a series of threads that go into the bath and out into the subsequent processes.
Q. Okay. Now, we're talking about the bath. After the suture passes through the bath, then what happens next? Let's just take the next step and stop there, just go through the next step.
A. Okay, now the suture comes out, and you have to wipe off the excess solution of resin and polymer. So we go through something called a pressure pad, a clamped pressure pad. It's like a squeegee. And what's happening is, there's pressure, and as we're pulling the wet coated suture through, we're wiping off the excess.
Q. Okay. After you go through the clamped pressure pad, then what happens to the suture, the braided suture?

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A. Now, remember I said this is clamped, so this is clamped. It's holding down the sutures. We have to pull the suture through this pad and into this oven which does heating and stretching.
Q. Okay. Now, the oven, can you describe the oven for us?
A. Yes, I can. This is a typical what we call a convection oven. It blows hot air into these different zones to help evaporate the Xylene. So there are four different zones, and it's set to different temperatures that we'll discuss in a minute, and it evaporates the solvent.
Q. Okay. Now, you said it evaporates the solvent. Does the oven have any other purpose?
A. Yes. The oven, in conjunction with the back friction of these pads, gives you this heat-stretching process, which tends -- which pulls on the suture, and it's being heated and stretched at the same time. And as Dr. Steckel said and I'm saying, it densifies it, and it makes it a smoother surface.
It also anneals the structure, in that it takes out what we call the residual stressors. Residual stressors are important because if you don't take those out, the suture will snarl and kink up when it's free.
Q. Okay. Now, can you describe -- you said it's a four-stage oven. Can you describe the temperatures in the oven?
A. Yes. While it is a four-stage oven, it can be set for

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four individual temperatures, Pearsalls set it up that the first two stages are set to the water boiling temperature, 212 degrees Fahrenheit, and then it moves on to 266 degrees Fahrenheit, and then on to 338 degrees Fahrenheit. So it moves up.
Q. Okay. And about how fast is the suture moving through this whole process?
A. It's going roughly like this, about one foot a second.
Q. And what's the specification that Pearsalls uses?
A. Well, they say 20 meters per minute.
Q. And that works out to be --
A. About one foot a second.
Q. Okay, great. Now, in making FiberWire, does Pearsalls use this process just one time?
A. No. What they do is, they run the suture through the coating, stretching, and heating oven once. Then they take it off that spool -- they take that spool it's wound on, and then they run it through again. So it goes through the coating, stretching, and heating process twice.
Q. Okay, thank you. I want to talk a little bit more about the stretching process and have you explain that, and we have a demonstrative exhibit for that, and so if you can go back up to the witness stand, Dr. Brookstein.
(Witness returns to the stand.)
MR. BONELLA: I'm going to put a slide up,

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PowerPoint slide.
Q. Exhibit 628, please. Thank you. Exhibit 628 is a demonstrative exhibit that you created?
A. Yes, it is.
Q. Can you explain how -- or, first of all, what is this a demonstrative exhibit of?
A. This is a demonstrative exhibit of what we saw in that schematic a few minutes ago of the pressure pads which are used to wipe off and put a back force on the sutures as it's going through the stretching and heating oven.
Q. Can you explain in this Exhibit 628 what is happening?
A. Yes. To the left of the pads, the sutures are under minimal tension. And then, remember, they've gone through the bath, and then when they go to the pads, you have to pull the suture through the pads. Remember I told you that the pads are tightened down onto the suture, so you have to pull it through, and in doing so, you develop the tension.
Q. Okay. And how tightly are those pads tightened?
A. I remember we asked the people at Pearsalls. They tighten them as tight as they possibly could.
Q. Okay, thank you. That describes Pearsalls' manufacturing process. Now I'd like to get to your infringement opinion --
A. Yes.
Q. -- and have you describe FiberWire. Are you familiar

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with Claim 1 of the '446 patent?
A. Yes, I am.
MR. BONELLA: Permission to publish Exhibit 618, Claim 1 of the '446 patent.
THE COURT: Fine.
MR. BONELLA: Could I have Dr. Brookstein step down again?
THE COURT: I don't think he has to. Isn't it on the screen? He can go through it on the screen. You all have it on your screen, right? Yes. I mean, you can put it up there if you want, but it's awkward when he comes down, and we don't have the mike and they all have to move, so --
MR. BONELLA: That's fine.
Q. The first part of the claim of the '446 patent says "a surgical suture"?
A. Yes, sir.
Q. Did you find that element present in FiberWire?
A. Yes. FiberWire is a surgical suture.
Q. Okay. And I'd ask you when you find these elements satisfied, if you could check them off.
A. Yes, that's checked.
Q. Thank you. Okay, the "consisting essentially of" part, I'd like to come back to that part. The next part after the "consisting essentially of" is "a heterogenous braid composed of a first and second set of continuous and discrete

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yarns," and it continues on. I'd like to just break that up. A heterogenous braid, does FiberWire have a heterogenous braid?
A. Yes, it does. It's composed of two sets of multifilament yarns.
Q. And what yarns are those?
A. They are PE and PET.
Q. And the heterogenous braid of FiberWire that it has is composed of a first and a second set of continuous discrete yarns?
A. That is correct.
Q. And the first set of continuous discrete yarns is what?
A. The first set is PE.
Q. And the second set of continuous discrete yarns is what?
A. PET.
Q. The heterogenous braid in FiberWire, is that a sterilized braided construction?
A. Yes.
Q. Now, the heterogenous braid in FiberWire, is there at least one yarn from the first set that is in direct intertwining contact with the yarn from the second set?
A. Yes, there is.
Q. And what yarns are those?
A. It's the PE yarns and the PET yarns that are in direct intertwining contact.

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Q. Are those the yarns in the braided sheath?
A. They are the yarns in the braided sheath.
Q. Okay. And did you find that element satisfied in FiberWire, the heterogenous braid element?
A. Yes, I did.
Q. Okay, could you please check that off.
(Witness complies.)
Q. The next element is, "Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of," and then we have our chemical names. Let's break that one up and take it slowly. It says "each yarn from the first set." Does FiberWire have a yarn from the first set?
A. Yes, it does.
Q. And what is that yarn?
A. PE.
Q. Okay. And the PE that FiberWire has from the first set, is that the PE in the sheath?
A. That is the PE in the sheath.
Q. Okay. And the FiberWire PE that is in the sheath, is that composed of a plurality of filaments?
A. Yes, sir. It's a multifilament yarn.
Q. Is the PE in the sheath of FiberWire composed of a plurality of filaments of a first fiber-forming material?
A. Yes, it is.

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THE COURT: What does that mean in English?
THE WITNESS: It means that the first set of yarns are PE yarns, the continuous filament yarns.
THE COURT: What's a filament?
THE WITNESS: Filaments are the individual fibers that are grouped together to make the yarn.
Q. Do you see where it says "the group consisting of," and it has a variety of materials listed there?
A. Yes, sir.
Q. So how many materials does FiberWire have to have to find infringement?
A. Just one.
Q. And which one does it have?
A. The PE.
Q. Okay. Did you find that element satisfied, the element starting with each yarn?
A. Yes, I did.
Q. Could you check that off, please.
A. Yes.
(Witness complies.)
MR. BONELLA: Just let the record reflect that Dr. Brookstein has checked off the surgical suture element, the heterogenous braid element, and the Element A, each yarn, in Plaintiff's Exhibit 618.
Q. The next element, Dr. Brookstein, it says, "Each yarn

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from the second set is composed of a plurality of filaments of a first fiber-forming material selected from --"
THE COURT: No, I think you read that wrong.
Q. Oh, I'm sorry. Let's just take it slower. This element, "Each yarn from the second set," does FiberWire have an each yarn from the second set?
A. Yes, it does.
Q. And what is that yarn?
A. It's PET.
Q. And where is that PET found in FiberWire?
A. It's found in the sheath of the braid.
Q. And does FiberWire have -- the FiberWire PET, is that composed of a plurality of filaments?
A. Yes, it is.
Q. And is that FiberWire PET composed of a plurality of filaments of a fiber-forming material?
A. Yes, it is.
Q. And so is the yarn from the second set that's composed of a plurality of filaments of a fiber-forming material selected from a group consisting of PET, nylon, and aramid in FiberWire?
A. Yes, it is.
Q. And which material is it selected from there?
A. From PET.
Q. Okay, did you find the Element B satisfied in FiberWire?

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A. Yes, I did.
MR. BONELLA: Let the record reflect that Dr. Brookstein checked off the Element B in Plaintiff's Exhibit 618.
Q. Now, the last element is "optionally a core." Does FiberWire have optionally a core?
A. Yes, it does.
Q. Did you find that element satisfied?
A. Yes, I did.
Q. And can you check that box off.
A. Yes, sir.
MR. BONELLA: Let the record reflect that Dr. Brookstein --
THE COURT: I don't know that you need to do that after each one.
Q. The last element is "consisting essentially of," Dr. Brookstein.
A. Yes.
Q. And I want to talk a little bit about that one now and focus our time on that. Consisting essentially of, what did you understand that to mean in order to determine infringement?
A. It means that you could have other items that are not listed in the claims, unlisted items, as long as they have no material effect on what's going on in these claims, what

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these claims describe. So you could have unlisted materials --
MR. SABER: Your Honor, objection. This is all the legal testimony. And it's wrong.
THE COURT: You know, no comments.
MR. SABER: I'm sorry, your Honor.
THE COURT: What's the question?
Q. In your analysis to determine whether there was a material effect on the coating for FiberWire, what did you -- what did you -- what was your analysis generally?
THE COURT: I'll allow this as to his state of mind, but, don't forget, it's that claim construction I handed to you that controls.
And I'm assuming you've seen that claim construction, is that right?
THE WITNESS: Oh, yes. I'm sorry. You were speaking to me.
MR. BONELLA: Well, let me just take it a little slower then, your Honor.
THE COURT: Before you take this off, we're going to print out this page.
MR. BONELLA: Okay, thank you, your Honor.
THE COURT: Mr. Alba, if you could print it. We may have just lost it. Someone just switched it.
Q. Dr. Brookstein, did you review the Court's claim

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construction?
A. Yes, I did.
Q. Did you review its claim construction and order of the novel and basic characteristics of the invention?
A. Yes, I did.
Q. I'd like to show you Plaintiff's Exhibit 632. Do you recognize this as the basic and novel characteristics of the invention?
A. Yes, I do.
Q. Okay, did you use this in your analysis to determine whether the "consisting essentially of" element was satisfied?
A. Yes, I did.
Q. And what were you looking for to determine whether the "consisting essentially of" element was satisfied?
A. I was looking to see if there were any unlisted elements that had a material effect on the basic and novel properties.
Q. Okay. And those basic and novel properties are the ones defined in the Court's order?
A. Yes, sir.
Q. Okay. Does FiberWire have any additional elements that are not in Claim 1?
A. Yes, it does.
Q. And what is that?
A. A surface coating.

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Q. So what were you comparing when you were doing your analysis?
A. I was comparing if the surface coating had a material effect on the elements that are in the basic and novel properties.
Q. As defined in Plaintiff's Exhibit 632?
A. Yes, sir.
Q. Okay. Could I have Exhibit 619, please, Plaintiff's Exhibit 619. Dr. Brookstein, do you recognize Plaintiff's Exhibit 619 as the finding of the Court's novel and basic characteristics of the invention?
A. Yes, I do.
Q. Okay, the first one is "a surgical suture." Does FiberWire's coating have any effect on whether FiberWire is a surgical suture?
A. No, it doesn't.
MR. BONELLA: Do we need to stop, your Honor?
THE COURT: No. With all these bells and whistles we have, there's a way of printing out what's on the screen, and Mr. Alba is trying to figure it out, but it doesn't seem to be working. All right, keep going.
Q. So there was no material effect, you said?
A. There was no material effect that made this not a surgical suture.
Q. I'd ask you, where you find no material effect, if you

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would check that column off, please.
A. Yes.
Q. The next part of the novel and basic characteristics as defined by the Court was "composed of two dissimilar yarns from the list in Claim 1." The list in Claim 1, what's that referring to?
A. Those are the two sets of yarns, the PE and the PET.
Q. Okay. Does FiberWire's coating have any effect on whether the suture is composed of two dissimilar yarns of PE and PET?
A. No, it does not. There's no material effect.
Q. And if you found that element was satisfied, would you please check it off.
A. Yes, sir.
Q. The next one is "wherein at least one yarn from the first set is in direct intertwining contact with the yarn from the second set." Do you see that?
A. Yes, I do.
Q. What is direct intertwining contact?
A. That would be a description of the braiding process where the yarns are intertwined, braided.
Q. Okay. And it says "at least one yarn from the first set." What's that referring to?
A. The first set would be the PE yarns.
Q. And it's referring to one yarn from the second set.

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What is that?
A. That would be the PET.
Q. So overall what is this element describing?
A. It's describing the braiding process of the PE and the PET.
Q. Okay. Now, did you come to an opinion of whether FiberWire's coating had any material effect on whether FiberWire's PE and PET braided?
A. Yes, I did.
Q. And what is your opinion?
A. It has no material effect.
Q. Okay, could you check that off, please.
A. Yes.
Q. Okay, now, the last one of the basic and novel characteristics refers to "so as to improve pliability and handleable without significantly sacrificing the physical properties of the constituent elements of the suture." That's a lot. Let's break that up.
Pliability, I want to talk about pliability a little bit. Let's describe to the jury what pliability means, and if I could have --
THE COURT: Actually, can I see counsel just for one second at side bar?
SIDE-BAR CONFERENCE:
THE COURT: While I was doing the jury charge, I

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focused on something that you both agreed on but I hadn't ever focused on before. The standard is actually what somebody of ordinary skill in the art would understand something to be. Now, you both agree on it, so it must be right. And just as you're framing things, now, let me just make it clear, does anyone -- is there a dispute as to who that person is?
MR. BONELLA: We put in a stipulated fact on that, your Honor. We agreed to that.
THE COURT: There are thousands of stipulated facts, so it's one I haven't focused on.
MR. BONELLA: It's agreed.
THE COURT: Well, somebody should say what it is because that's the way the question is asked, isn't it? Well, who is someone of ordinary skill in the art? Does anyone remember? Whatever it is, we need to figure that out. And I don't know how you ask this because it's, is it not, it's what somebody of ordinary skill in the art would understand the material effect is, right? Everyone agrees on that, right?
MR. SABER: Yes.
MS. MALINOSKI: Yes.
THE COURT: And I don't know if you all agree on -- there's a stipulation somewhere as to what that is, right?
MS. MALINOSKI: We agreed to their definition of a

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person of ordinary skill in the art.
THE COURT: Just make sure it's phrased consistent with what you both asked for, but, more importantly, you agree that's the standard. I think you do, right?
MR. SABER: Oh, yes, that's the law.
THE COURT: That's the law, okay, all right.
(End of side-bar conference.)
MR. BONELLA: Your Honor, I have that information. The stipulated fact is, "A person of ordinary skill in the art is a person having undergraduate --"
THE COURT: Now, just slowly so they can understand it. So the standard here is, what does somebody of ordinary skill in the art understand? So they've agreed on who that person is. That's a stipulation, which means that you can accept it. So why don't you slowly so they can understand.
MR. BONELLA: Sure. "A person of ordinary skill in the art is a person having an undergraduate degree in engineering or science and several years, approximately three to five years experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications."
Q. Dr. Brookstein, let me ask you, are you a person of ordinary skill in the art?
A. Yes, I am.
Q. Do you have at least an undergraduate degree in

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engineering or science?
A. Yes, I do.
Q. And do you have several years, at least three to five years experience with the manufacturing and/or processing of fibers and sutures?
A. Yes, I do.
Q. And is that experience with fibers and sutures that can be used for biomedical applications?
A. Yes, that is.
Q. When you're doing your analysis to determine what is a material effect, are you determining it from a person of ordinary skill in the art?
A. I didn't -- could you repeat that?
Q. Sure. When you're doing your analysis to determine whether FiberWire's coating has a material effect on the novel and basic characteristics, are you doing it from a perspective of a person of ordinary skill in the art?
A. Yes, I am.
Q. Thank you. So we're going to talk a little bit about pliability, and I'd like to go to Plaintiff's Exhibit 629, if I could. I'd like to explain what pliability is, Dr. Brookstein, so we can help understand the novel and basic characteristics.
Okay, this graphic, did you prepare this?
A. Yes, I did.

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Q. And this is a demonstrative exhibit?
A. Yes, it is.
Q. Okay, what are we looking at here?
A. We're looking at something that would be what we call a monofilament, a single homogeneous cross-section of a fiber.
Q. Okay, can you just briefly and generally, what is pliability?
A. Pliability is a way to discuss or describe how much something can bend, how much load it takes to bend something.
Q. And can you contrast that with maybe pulling on something?
A. Yes. We can take a structure, a linear structure like this monofilament suture, and we can pull on it, and that would be putting some tension, and we'd be measuring the tensile properties. Or we can bend it, and we're measuring what we call the bending properties or the pliability properties.
Q. Okay. And what we have here you said diagrammatically is a monofilament suture?
A. This one is a monofilament, that's correct.
Q. Now, a monofilament suture, its pliability is a function of what parameters?
A. It's a function of its diameter.
Q. And what do you mean by diameter?
A. The D, the distance from one end of one -- I'll just do

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this. That's the diameter, okay?
Q. Okay, what else is a monofilament suture pliability the function of?
A. It's also a function of what we call the suture modulus. Modulus is a way to describe how much resistance there is when you pull on something, okay? So the higher the modulus, the stiffer it is when you pull on something.
Q. Now, you just said pulling, and we're talking about bending.
A. That's correct.
Q. And you use those two concepts?
A. Yes, because what happens is, when you bend something, in fact on the outside of the bend you're stretching it, and on the inside of the bend you're compressing it. So that's why we use the tensile properties to help you determine what the bending properties are.
Q. Is that always true, or is that just true for monofilaments?
A. That's only true for monofilaments. It's only true for monofilaments.
Q. Okay. Now, the next element you have there is the suture cross-sectional geometry. Can you explain what that means and how that relates to pliability.
A. Yes. I show here a circular geometry, but as you might imagine, you can have geometries that are not circular, that

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is ellipticals, and they would have different pliabilities. So it's a function of what the actual shape is of the suture.
Q. Okay, that's a monofilament type structure, right?
A. That is correct.
Q. Okay. Could I have Exhibit 630, please, plaintiff's exhibit. Okay, generally what is this exhibit?
A. This is an exhibit I drew to describe the pliability of the multifilament suture that's found in FiberWire.
Q. So FiberWire is not a monofilament, right?
A. No. FiberWire consists of 16 multifilament yarns.
Q. Okay. Can you generally describe -- you have a lot of circles on the screen here. Can you describe generally what these circles are.
A. Yes.
THE COURT: Well, go back. What's the difference between a fiber and a filament?
THE WITNESS: A filament, all filaments are fibers, but all fibers aren't filaments. What I mean --
THE COURT: Got it?
(Laughter.)
THE WITNESS: This is going to be fine in a minute. Let's say you are making a sweater, okay? You're making it from wool yarn, and they're individual fibers. We call those staple fibers. We twist it together, and we have these staple fibers.

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Synthetic fibers such as what we have here are made in a continuous fashion, and they're called continuous filaments. You can cut them up into staple fibers, but for these type applications, you use them in a continuous filament.
So all filaments are fibers, but all fibers are not filaments. I hope that helps.
Q. So, Dr. Brookstein, can you explain what the circles are we're looking at here.
A. Those circles, the little circles are a depiction that I made of the cross-section of the multifilament yarns that are in the FiberWire.
Q. So let's just take it, slow down here. The blue circles and orange circles, so the blue circles represent what?
A. The blue circles represent the PET multifilament yarns.
Q. And what do the orange circles represent?
A. The orange circles represent the PE multifilament yarns.
Q. Okay, so now we have groups of them on the outside. What do the groups of the orange circles on the outside mean?
A. They would represent the eight yarns that are going in one set, and the other color would be the eight yarns going in the other set.
Q. Okay. So all the orange ones on the outside are the polyethylene?
A. All the orange ones represent the polyethylene on the

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sheath, that's correct.
Q. Okay, how about the blue, what does the blue represent?
A. The blue represents the PET that's going in the other direction.
Q. Okay. Now, inside we have three groups of orange circles. What are those?
A. Those would be the core yarns.
Q. And so the outside is called the what, the outside circle?
A. The outside is called the sheath, and the inside is called the core.
Q. Okay. Now, let's talk about the pliability concept of a multifilament suture such as FiberWire. Can you explain what a multifilament suture pliability such as FiberWire is a function of, please.
A. Yes. For the multifilament, now each individual fiber contributes to the bending, okay. So what you do is, you add up the pliabilities of all the individual filaments, and then you get a total pliability.
Q. So let's just stop right there. So you said the individual filaments. Could you just give us an example of what you mean in a demonstrative by an individual filament.
A. Yes. What you would do is -- I'm going to try my best here -- you would determine what the pliability is of -- I can't do it -- that one of those little circles is, and that

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would be the pliability of that filament in that yarn.
Q. And, now, how does that contrast to the monofilament?
A. In the monofilament, you make your determination based on the entire diameter, so it's acting as one monolithic structure. Here it's the individuality that becomes important.
Q. Okay. Now, we're talking about the number of filaments. The next one is going to need some explanation. Filament moduli, what are we talking about there?
A. That would be similar to what we had for the monofilament. That would be the resistance to stretching of each individual filament.
Q. And you said resistance to stretching. We're talking about bending. How does that relate?
A. Well, again, as I said for the monofilament, you look at the resistance to stretching this way. And then the inside of a multifilament fiber -- a fiber is in tension, and the -- excuse me -- the outside is in tension. The inside is in compression. You could be thinking that each one of these individual little fibers is like a monofilament, but the diameter is so much smaller, it acts differently.
Q. So a multifilament suture, in other words, is made up of many, many, many monofilament fibers?
A. Yes, thousands of monofilaments.
Q. Fibers. And FiberWire, there would be thousands, right?

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A. The individual single fibers, I never counted the actual number of fibers. It's a lot.
Q. Now, the next element is fiber diameter. What are we talking about there? And you have the D label there?
A. Yes. Again, there you would be, if you looked at -- just pick any one of these little circles, and you would want to know the diameter of that fiber or filament, that would be part of what determines the pliability of the structure.
Q. Okay. And, now, the last thing you have is fiber-to-fiber mobility --
THE COURT: So that's the diameter of not the entire circle you see here. That little one you circled up above, for example?
THE WITNESS: That is correct.
Q. And so that is in contrast to the monofilament?
A. The monofilament, you look at the entire diameter.
Q. Okay. Now, the last one is fiber-to-fiber mobility and lubricity. Can you talk about that and explain how that relates to a multifilament suture pliability.
A. Yes. This is the real essence of why we use textile products in many applications. In textile products, we allow the fibers to slide by each other, and in doing so, it makes them not as stiff. You would never wear a shirt that was made out of monofilament. It would be too stiff. But when you have multifilaments, it allows it to be pliable. And why

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is that? Because the fibers can slide by each other, and each fiber can act independent of the fiber that it's next to. This is the key element in most textile operations.
Q. In contrast with the monofilament, the fiber-to-fiber mobility, how does that contrast with a monofilament type structure?
A. Well, if you -- you're going to have to do a little -- if you thought the monofilament itself was composed of a lot of little sub-elements but they're not allowed to slip by each other, it would be very stiff. But this is not very stiff because the fibers can slide by each other.
Q. Okay. Now, we see lubricity on there. How does that relate to monofilament -- or multifilament suture pliability?
A. Well, just because you have multifilaments, okay, that in and of itself doesn't mean it's going to be flexible, because if those multifilaments are bonded to each other to prevent them to move, you're going to get back up to having a very stiff structure. But if we have a structure where there's lubricity or slipperiness between the fibers, then it can slip, and you get the benefit of the multifilament pliability.
Q. Now, well let's go back to FiberWire for a second. FiberWire's braided structure consisted of what materials?
A. It consisted of the slippery polyethylene and the PET yarns.

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Q. And you said the slippery polyethylene.
A. Yes.
Q. Describe a little bit about that, what you mean by that.
A. Polyethylene is known by everyone who works in this field as being a very slippery and lubricious material. I said earlier it's an inert material; it's hard to get something to stick to it. So polyethylene, it's similar to Teflon, it's very slippery.
Q. Okay. So how does FiberWire's pliability, when you look at FiberWire's pliability, what are the things that are contributing to its pliability?
A. Because -- well, two things are happening. One, because you're allowing the PE multifilament yarns, the fibers within themselves can slip, that decreases the pliability. And then because of the intertwining contact, you have a chance for the actually multifilament of the PET to slip relative to the other yarns. So it's helping you in two ways, but it's all based on the slipperiness of the PE.
Q. Okay. I'd like to go back, if I could, to the Court's novel and basic characteristics. I believe that's Plaintiff's Exhibit 619, and if you could recheck off the ones that you had checked off before, Dr. Brookstein.
(Witness complies.)
Q. Okay. So what we did, we talked about pliability. Now I'd like to talk about that last section. We talked about

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what pliability is, and it says "so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture." What do you understand the physical properties of the constituent elements of the suture, what's the constituent elements that it's referring to there?
A. Well, the constituent elements are the fibers, the PE and the PET.
Q. Okay. Now, did you reach an opinion as to whether FiberWire's coating has a material effect on this last part?
A. Yes, I did.
Q. And what is your opinion?
A. That the coating has no material effect on the last part of these novel and basic characteristics.
Q. Now, in forming your opinion, were you looking to see whether FiberWire's coating had any effect?
A. No. I was looking to see if it had a material effect.
Q. Okay. Can you explain just generally the things, the basic reasons why you think FiberWire's coating does not have a material effect on this last element of the novel and basic characteristics.
A. I looked at a lot of different documents. I looked at how it was made. I looked at the patent. I looked at the data that Pearsalls gave us. I looked at what you'll see later Dr. Burks said. And from all those, I concluded there

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was no material effect on the last element in the novel and basic characteristics.
Q. Okay, let's talk about FiberWire. In making your determination that there was no material effect, did you analyze the FiberWire structure?
A. Yes, I did.
Q. Tell us some of the things that you did, just generally tell us some of the things that you did in analyzing the FiberWire structure.
A. I determined how much coating was on it, I determined where the coating was, and I determined if it affected the structure of the FiberWire.
Q. Okay, let's break that down and talk about each one of those things individually. The first thing you said is, you determined, I believe, how much coating was on the FiberWire product.
A. Yes.
Q. How much coating did you determine was on the FiberWire product?
A. At the final stage of manufacturing, 4.8 percent by weight. So 4.8 percent of the weight of FiberWire was coating.
Q. Okay. And how did you go about doing that?
A. Using a standard technique in our textile testing labs. You take a length of material uncoated. You weigh it. Then

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you take the same length with coating on it, and you weigh it, and you compare the two, and you find out it's about 4.8 percent by weight.
Q. And you did that. Do you recall our visit to Pearsalls?
A. Yes, I do.
Q. What did Pearsalls say about how much coating is on FiberWire and whether they could determine it?
A. They said it was minimal.
Q. Okay. Let's talk about, when you say it's 4.8 percent by weight is the coating, how much of the suture by weight is not coated, is not coating? Let me rephrase that question. How much of the FiberWire suture by weight is not coating?
A. I'm not sure I understand your question, but let me say this: 70 percent of the material is fiber. In the circle of the suture, 70 percent is material. Only 4 percent is resin, and the rest is what we call voids, airspace.
Q. The weight overall of FiberWire is made up of the coating?
A. The coating and the constituent elements.
Q. Okay, so when you weighed it and you got 4.8 percent was the coating, what was the rest?
A. The rest was the FiberWire, the yarns, the yarns.
Q. Okay, and so the 4.8 percent was --
A. Just the coating.
THE COURT: By resin, you mean the coating?

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THE WITNESS: I'm sorry, sometimes you'll hear me use the word "resin." I mean coating. "Resin" is a broad term, but we're really talking about a surface coating here.
Q. So if I subtract 4.8 percent from 100 percent, that's --
A. That would be the FiberWire, about 95 percent, yes, sir.
Q. And that about 95 percent is all yarn?
A. Yes, that is correct.
Q. Okay. Let's talk about some other things you mentioned is you weighed it, and one of the other things you mentioned you did was, I think you looked at FiberWire?
A. Yes. I spent a significant amount of time looking at samples of FiberWire under what we call a scanning electron microscope, which is a tool to really get in and see what's going on.
Q. Let's talk about a scanning electron microscope. What is a scanning electron microscope?
A. Okay, it's a laboratory device that is used in all kinds of materials laboratories to really focus in on the microscopic properties of in this particular case sutures. Medical people use it for pathology. There's a whole range you can use it, but it's much stronger than an optical microscope, in that it allows you to really see what's going on inside, in this particular case, the FiberWire.
Q. Is that a device you've used throughout the course of your experience?

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A. I have used scanning electron microscopes for over thirty years. Almost every textile structure that I've worked on I look at under a scanning electron microscope.
Q. Are you able to take pictures, photographs of the scanning electron microscope?
A. Yes. It's probably one of the precursors to all the new technology today. It's actually on the screen. It's like a TV screen, so you can adjust what you're looking at. And then once you have what you want, you can then hit a button and get a printout.
Q. Did you take pictures of the FiberWire that you looked at under the scanning electron microscope?
A. Yes, I did.
Q. Okay, let me start with Plaintiff's Exhibit 284, the physical sample. And this is FiberWire that has not been coated, heated, stretched at all, and I would like to show that to you.
MR. SABER: Excuse me, Mr. Bonella. It wasn't in the book. Do you have something?
MR. BONELLA: It's the sample, physical sample.
MR. SABER: Oh, I thought you were going to use it in the book, but that's okay. May I take a quick look at it, your Honor?
THE COURT: Yes.
THE WITNESS: Mr. Ficocello, can you get rid of

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these check marks?
Q. Do you recognize Exhibit 284, Dr. Brookstein?
A. Yes, I do.
Q. What is it?
A. This is a sample that we got when we went to Pearsalls of what we call the scour dyed or the uncoated FiberWire US 2.
Q. Okay. And so this sample has not been heated, coated, or stretched?
A. It has not been coated, and it has not gone through the heating and stretching oven.
Q. But does it have the braiding of the yarns?
A. Yes, it does.
Q. Okay. Were you able to take a picture on your scanning electron microscope of Plaintiff's Exhibit 284, the uncoated, unheated, unstretched FiberWire?
A. Yes, I have been able to take a picture of that.
MR. BONELLA: Your Honor, permission for Dr. Brookstein to come down and explain the picture that he took, and that's going to be Plaintiff's Exhibit 499.
THE COURT: Can you put it up on the screen?
MR. BONELLA: I can, but I think it would be very good to show the jury the exhibit.
THE COURT: All right.
MR. BONELLA: Because it's such a small thing and

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we have it blown up.
(Witness in front of the jury.)
Q. Dr. Brookstein, we're looking at Plaintiff's Exhibit 499. Can you identify it for us, please.
A. Yes. This is the scanning electron micrograph I took of the specimen that you had just given me, the uncoated, unheat-stretched FiberWire.
Q. Can you describe for us the surface of this suture, what we see here.
A. Well, again, this is a braid of the two dissimilar yarns, and what you see here is the bumpiness or the -- well, the bumpiness of the structure that's characteristic of the braid.
Q. Okay. And how about at the end here? What's going on down here at the end?
A. Well, you have to cut the specimen. Remember, it's a continuous suture. So when I cut it, this shows the individuality of the fibers splaying out at the end there.
Q. So and this is the uncoated, unstretched, unheated sample. Were the fibers inside FiberWire, were they bound together or --
A. No, not at all. They're individualized.
MR. BONELLA: Okay, I'll take this down, your Honor.
Q. Next I'd like to show you our next physical exhibit.

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MR. BONELLA: Your Honor, we have several blowup exhibits of these pictures. I don't know if it works better to have Dr. Brookstein stay here.
THE COURT: That's fine.
Q. I'd like to show you Exhibit 342. This is another FiberWire sample. Do you recognize this sample? I believe this is one that went through the stretching, coating, and heating process one time?
A. Yes, I do recognize this as a sample.
Q. And were you able to take a scanning electron micrograph of that sample?
A. Yes, I was. Yes, I did.
Q. Okay. Do you recognize Plaintiff's Exhibit 500, Dr. Brookstein?
A. Yes, I do.
Q. What is Plaintiff's Exhibit 500?
A. This is a sample of FiberWire that's gone through the coating, heating, and stretching process once. When I did my weight measurements, 3.4 percent of this surface has the Nusil coating on it. Remember the two passes has 4.8. This has 3.4 percent coating on it.
Q. Now, can you describe the surface of that structure and how you saw it and how it's visualized in the picture.
A. Yes, that coating, that surface looks basically the same as the uncoated. Again you see the individuality of the

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braided yarns. You see the peaks and the valleys. You don't see anything coating over that.
Q. When you say peaks and valleys, when you say peaks, what are you referring to?
A. Well, you know, when you braid, you have this interlocking thing. So we'd say this part where the yarn goes over that part would be a peak, and when it goes underneath would be a valley. And the area, the space between that is what we sometimes call the peaks and valleys.
Q. Okay. And you said this had 3.4 percent of coating by weight on it?
A. That's what I measured.
Q. Okay. And how does that exterior surface -- if I could bring Plaintiff's Exhibit 499 back up and publish that -- how does the exterior surface of this single-coated FiberWire 3.4 percent coating in Plaintiff's Exhibit 500 compare to the uncoated sample that you looked at, Plaintiff's Exhibit 499?
A. I can't really tell the difference.
Q. And did you look at this under the microscope?
A. I looked at it under the microscope.
Q. How about the peaks and valleys between the two?
A. They looked similar to me.
Q. Okay. Let me ask you before we move on about the internal structure on the single-coated FiberWire, Plaintiff's Exhibit 500. Were you able to look at the inside

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of the structure of the single-coated FiberWire?
A. Yes, I did in this picture.
Q. Okay, can you describe the inside structure of FiberWire that you were able to see on this single-coated FiberWire?
A. This is the inside area here, and what I was looking for to see if there was any resin -- excuse me -- coating penetration into the internal structure of the FiberWire, and I did not see it.
Q. Now, when you say you didn't see it, what did you see on the inside structure about the yarns and fibers?
A. I see the yarns still were similar to that. They're individualized. They're not individually coated. They're still free to move about. It looked very similar.
Q. If there was coating inside that structure, what would you have expected to see in the single-coated FiberWire picture, Plaintiff's Exhibit 500?
A. Well, one, you would see the coating, and you also would not see these fibers splaying out like that. It would be a nice clean cut.
Q. Okay. Now, how about the surface of the single-coated FiberWire in Plaintiff's Exhibit 500, were you able to see the coating on the surface?
A. Not really, no.
Q. But is there coating on there?
A. Yes. I measured it to be 3.4 percent, yes.

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Q. So where is the coating?
A. If you look carefully, you might see a very thin film in some areas of the structure. It's not that much coating to begin with, so --
Q. Okay, next I'd like to look at a double-coated sample. That's Plaintiff's Exhibit 389. Do you recognize Plaintiff's Exhibit 389?
A. Yes, I do.
Q. Now, is that a FiberWire sample that was heated, stretched, and coated?
A. Yes, it was.
Q. Were you able to take a picture with your scanning electron microscope of Plaintiff's Exhibit 389?
A. Yes, I did.
Q. Okay. And let me show you Plaintiff's Exhibit 554. I'll get these on the right side up eventually.
MR. SABER: Can I help you, Mike?
MR. BONELLA: If you don't mind, that would be great.
MR. SABER: Sure.
Q. What do we have in Plaintiff's Exhibit 554, Dr. Brookstein?
A. This is a specimen of a coated FiberWire that's coated, heated, and stretched.
Q. Is this the exterior surface?

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A. That would be the exterior or the surface of the sheath.
THE COURT: So is this the single or.
MR. BONELLA: Double coated, your Honor, double coated.
THE COURT: No, just, Dr. Brookstein, what is it?
THE WITNESS: Double coated.
THE COURT: This is the double coated?
THE WITNESS: Yes.
Q. Dr. Brookstein, in addition to double coating, are there any other differences between the suture that would be Plaintiff's Exhibit 554 and the single-coated suture that was in Exhibit 342, the physical sample?
A. It's been heated and stretched an additional time.
Q. Now, if we look at the exterior surface of FiberWire here, what do you see?
A. I see individuality of fibers. I do see little elements. These would be little elements of coating. Remember I said earlier that coating doesn't stick to polyethylene, so you would expect to see little globules of coating within the structure.
Q. Okay. How about the peaks and the valleys?
A. Well, first of all, there's no -- there's nothing filled in here, so you still have the peaks and the valleys. But you are heating and stretching, so the peaks and the valleys are beginning to be smooth, but not because of coating. It's

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because you're heating and stretching. But you still see there's no resin in there, there's no resin in there, coating in there, there's no coating in here, there's no coating in there.
Q. When you looked at it and you looked at it in the picture, how do the peaks and valleys in Exhibit 554 compare to the peaks and valleys that you looked at in the uncoated and single-coated samples?
A. Essentially the same.
Q. Okay. Let me ask you a question. Were you here for Mr. Saber's opening statement?
A. Yes, I was.
Q. Okay. During Mr. Saber's opening statement, he said, "FiberWire's coating smooths out the braid." Do you agree with that?
A. Not at all.
Q. Why?
A. The pictures show that it doesn't smooth out the braid. Here are braided, coated, heated and stretched FiberWire. I do not see any smoothing out here or any filling in.
Q. If it was smoothing out the braid of the exterior FiberWire, what would you expect to see?
A. You would see a film that goes over this. You would see a filling in of this region here and this region here. You might not not even be able to see the fibers. It would cover

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it up as a little jacket. I don't see that.
Q. Okay. How about the individual filaments on the exterior of the FiberWire, Exhibit 554, were you able to see those?
A. Yes.
(Witness indicating.)
Q. Let me show you Plaintiff's Exhibit 553. Do you recognize Plaintiff's Exhibit 553?
A. Yes, I recognize it.
Q. It's still upside down. What is Plaintiff's Exhibit 553?
A. This is a cross-section of the double-coated FiberWire.
Q. So is that a cross-section of the sample of Exhibit 389, the double-coated sample we had?
A. Yes, it is.
Q. Okay. What are we looking at in Exhibit 553?
A. We're seeing the individual multifilaments. We're seeing that they're not bonded together. We're seeing only multifilaments in here. We're seeing no coating.
Q. Now, if this was coated, if coating was in here, what would you expect to see?
A. You would actually, you would see this all filled in here. It would be like islands in a lake. You would actually be able to see that, but you can't see that.
Q. Now, there's different brightness, like in this area

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here relative to this area here, bright here relative to that. Is that coating?
A. No. That's typical of a scanning electron microscope. What happens is, you don't get every single fiber perpendicular to the beams, so sometimes you get these little artifacts in there. That is definitely not coating.
Q. Is that a function of the light, the exposure?
A. The electron beam, yes. It's not coating.
Q. Okay, how about over if we look back at Plaintiff's Exhibit 499, the end of the suture where you cut it, these parts here, what is that?
A. Well, those are the individual fibers, and again you can see that they are spreading out.
Q. Now, how about this part here? Is that part of fibers coming together, or is that part of the --
A. No. Again, that's an artifact. When you cut, sometimes you'll get something that looks like they're together, but they are not stuck together.
Q. And when we're talking about the end of the suture, we're talking about Plaintiff's Exhibit 499?
A. Yes, sir.
Q. Dr. Brookstein, did you create a demonstrative to help explain how your analysis of FiberWire where its coating was relates to pliability?
A. I created that demonstrative, yes, I did.

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Q. Okay. Is this a demonstrative you use to teach with?
A. I have used not this particular one but the same one for almost thirty years that I've been teaching about yarn mechanics and bending and pliability of structures like these sutures. It's my touchstone.
Q. Can you explain with reference -- this is demonstrative Exhibit 613. Explain what you have in demonstrative Exhibit 613, and then we'll talk about the sutures, but let's just stick to the Exhibit 613. Explain the three sets of cards.
A. We have three sets of cards -- and I'm not going to do a card trick here -- we have three sets of cards and one set with 16 cards, and they're all individual, okay, 16 cards, and I punched a hole and secured them to this board, okay. Then I took over here the same 16 cards, and I glued each one together, so card 1 got glued to 2, 2 to 3, and so on. So these are all glued together. And then in the middle here I have a kind of an intermediate situation where I have 16 cards, but I've glued 1 and 2 together and 15 and 16 together.
Q. Okay. Now, with Plaintiff's Exhibit 613, can you explain the pliability concept to the jury.
A. Yes.
Q. And how it varies.
A. Remember earlier I talked about monofilament versus

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multifilament. When they're all glued together, this would be an analog to a monofilament.
Q. You used the word "analog." What's that?
A. It would be a model. It would be similar to the -- it would be comparable to what you'd have if you had a monofilament where everything was all one structure, okay. So I did that.
This over here would be the example or similar to a multifilament where you had 16 individual materials, each one having its own set of properties, and you were going to see how that bent, okay. And then the middle one would be, all right, I'm going to have a little bit of coating, if you will, on the outside, so I'm going to glue 1 and 2 and 15 and 16.
Q. Now, how does the bending or pliability compare? Can you describe how that works?
A. Yes. Okay, and my hand is not calibrated, but, okay, that's -- they're free to slide by each other, okay? Here they're not free to slide by each other, okay? I can't bend that. This is very rigid. The same cards, but these are glued together. These are not glued together. And this one where it's just 1 and 2 are glued and 15 and 16, it's about the same as this.
Q. When you say about the same as this, you're referring to --

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A. The one that 1 and 2 and 15 and 16 are glued together is about the same as they're not glued together. But you can see this, you can't --
(Witness indicating.)
Q. Now, how does that relate to the concept of bendability and pliability of FiberWire and what we've observed with respect to the FiberWire coating?
A. Well, we know FiberWire is made from multifilaments, and we can see from these pictures that the coating doesn't get into the structure. We can see that the coating doesn't bond the fibers together, okay? So these type of structures would be similar to these cards here that can bend. If the coating was into the structure, you'd have something like that.
(Witness indicating.)
Q. Okay. Now, in forming your opinion that FiberWire's coating does not have a material effect relative to the pliability in the novel and basic characteristics, does this relate to that?
A. Yes. Once I observed that the coating was not getting inside the structure and bonding these fibers together, then I knew that those fibers could act individually; and if they acted individually, it would be pliable.
Q. Now, does that go back to what we talked about before, the multifilament pliability and how that works?
A. Yes. These operate as multifilament structures where

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there is lubricity and there's freedom of motion between the fibers.
Q. Now, when talking about freedom of motion, we had that demonstrative up there. We had the little circles, the little diameter of filaments. How does that relate to what we see in FiberWire?
A. That's what it is. That picture we saw is a schematic representation of what's actually the case of FiberWire.
Q. Now, can you give us an example of a FiberWire coating if it was on FiberWire, not FiberWire's coating but a hypothetical coating, that could have a material effect on the pliability of FiberWire.
A. Coating can have a material effect if it gets inside and bonds all these together, yes.
Q. But does FiberWire have that type of coating?
A. Not at all.
Q. Oh, one other question. With regard to the handleability and the smoothness of the structures, you were able to see the exterior, the peaks and valleys?
A. Yes.
Q. From your examination, did you conclude whether FiberWire's coating had a material effect on the smoothness and the bumpiness of the structure, the peaks and the valleys?
A. Yes. FiberWire's coating had no material effect on

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smoothing out the peaks and valleys in the structure.
MR. BONELLA: Okay, if you could go back up to the stand, Dr. Brookstein.
(Witness returns to the stand.)
Q. In analyzing FiberWire, its pictures, weighing it, and look to the manufacturing of it, were you able to determine how FiberWire is applied and where it's applied?
A. How FiberWire is applied?
Q. How FiberWire's coating is applied? Sorry, I misspoke.
A. Yes, I have.
Q. And where is it?
A. It's only on the surface.
Q. Okay. Now, let's talk about the '446 patent. Did the '446 patent, is that something you considered in determining whether there was a material effect of FiberWire's coating on the novel and basic characteristics?
A. Yes, I did.
Q. Okay, if I could have the Plaintiff's Exhibit 130, please, Mr. Ficocello.
THE COURT: About how much longer do you have?
MR. BONELLA: I have quite a bit, your Honor.
THE COURT: What?
MR. BONELLA: I have about forty minutes.
THE COURT: Three minutes?
MR. BONELLA: Forty minutes.

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THE COURT: I thought you were going to be done. There's no way you can wrap this up by 1:00 o'clock?
MR. BONELLA: No way, your Honor.
THE COURT: We'll talk at the break. Keep going.
MR. BONELLA: Plaintiff's Exhibit 130, can we have Column 6, Lines 5 through 8. If you could highlight the first sentence, please, Mr. Ficocello.
Q. That first sentence, Dr. Brookstein, did you consider that in your analysis of whether FiberWire's coating had a material effect?
A. Yes, I did.
Q. And how is that a factor in your analysis?
MR. SABER: Objection, your Honor.
THE COURT: Overruled.
A. It starts with the words "if desired." It tells me that it's optional. It tells me that if you want to do something else to improve the handleability, you could conceivably do this. It says "if desired."
Q. How about the last sentence in that section, could you highlight that Mr. Ficocello, please. It's Lines 14 through 18, Column 6.
Did you consider that sentence in your analysis as to whether FiberWire's coating had a material effect?
A. Yes, I did.
Q. And how did that impact your analysis?

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 381-429
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY THREE
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 8, 2007 9:00 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

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at sidebar because they're not self-explanatory.
MS. MALINOSKI: Your Honor, we're removed any objections to the coating. There's no objection to the whole development of Orthocord from, you know, birth to when it came on the market as well as the market commercial kind of information.
THE COURT: I'll exclude a lot of that giving them some leeway, because I let you do your thing. Aren't you going to do that through a witness?
MR. SABER: Not about that because that was cross-examination in the documents. I'm not going to call an adverse witness. I'm not sure I understand the question, your Honor.
THE COURT: Why do you need this?
MR. TAMBURO: Just to prove what they know about coating when they were developing their own product.
MS. MALINOSKI: We're not objecting to that.
MR. TAMBURO: Okay. Well, I'll look at exactly what they're objecting to.
THE CLERK: All rise for the jury.
THE COURT: Good morning. Terrible day outside. I know one person was delayed.
THE JUROR: Sorry.
THE COURT: No problem. I expected that this morning when I drove in.

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DAVID STUART BROOKSTEIN, RESUMED.
DIRECT EXAMINATION, CONTINUED
BY MR. BONELLA:
Q. Good morning, Dr. Brookstein.
A. Good morning, Mr. Bonella. Good morning, your Honor.
MR. BONELLA: May I show this to the witness, your Honor?
THE COURT: You may.
Q. Dr. Brookstein, giving you smaller copies of Exhibit 499, 500, 554, 553 that have been labeled as according to what they were according to the manufacturing of the samples, are those exhibits labeled correctly in terms of the stretching, heating and coating processes that those sutures that you looked at underwent?
A. Yes, they are.
Q. I'd like to turn your attention to Exhibit 506 which is on the screen, we've highlighted the dye, the measure stage?
A. Yes, sir.
Q. What is this data?
A. This is data that was received from Pearsalls. It's batch data for a little over 300 testing specimens for prior shipment they do these tests.
Q. How is this exhibit compiled?
A. This exhibit, I understand Pearsalls sent to Woodcock &

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Washburn the batch data and then it was reduced to these tables.
Q. So it was compiled from batch data records of Pearsalls?
A. That is correct.
Q. Did you rely on this information?
A. Yes, I did.
Q. The dye stage, what is the construction of the suture of the dye stage?
A. The dye stage would be after braiding but before coating, heating and stretching.
Q. What does the construction do for the measure stage?
A. After coating, heating and stretching twice.
Q. Do you see the knot columns under each?
A. Yes, I do.
Q. What does that represent?
A. That is the data from the knot test.
Q. What's the knot test?
A. The knot test is where you tie a knot in the suture and pull on it and see what's the load value of the knot braids.
Q. It's the value of the knot braids?
A. Yes, sir.
Q. And how many batches of data did you look at?
A. A little over 300.

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Q. Okay. And what did you find? Did you compare the knot stage values of the dye samples against the knot stage of the measure samples?
A. Yes, I did.
Q. And what did you find?
A. I found that the average for the knot was 14.3 pounds and the average for the measure was 14.7 pounds.
Q. What does that tell you?
A. It tells me the measure after coating, heating and stretching is 2.7 percent greater than for the uncoated heated stretched.
Q. Is that a material difference?
A. No, it's not.
Q. How does it relate to the pliability and handleability characteristics?
A. It's common in textile engineering to use a knot test to determine what the pliability is of the material.
Q. Why is that?
A. Because when you tie a knot and bend it, when you a tie a knot, you bend the yarn or the suture that the knot is made from, and the outside of the bend, the stresses are positive, and the inside, the knot stresses are negative, which is exactly what happens in a bending test.
Q. So what were you able to conclude from these data relevant to pliability?

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A. I was able to conclude there was no material effect between the measure, which was the dye coated, and stretched and the uncoated stretched and heated. There was no material effect.
Q. Did you look at the diameter data from Pearsalls as well?
A. Yes, I did.
Q. What did you -- were you able to determine any difference in diameter between the unstretched, uncoated, unheated samples and the heated, stretched, coated FiberWire?
A. Yes, the uncoated heated and stretched are larger than the heated -- coated, heated and stretched.
Q. Why is that?
A. Because when you heat and stretch, you are smoothing out the braid and the braid is consolidated.
Q. And how does that relate to handleability?
A. That would be make it more handleable.
Q. More handleable due to what, Doctor?
A. Due to the fact that it's being smoothed because the heating and stretching.
Q. Does that affect the peaks and valleys?
A. Yes, that would make it smoother.
Q. Is that what you looked at under the photo micrograph due to the heating and stretching?

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A. Yes, sir.
Q. I'd like you to turn to Dr. Burk's testimony. Did you rely on Dr. Burk's testimony?
A. Yes, I did.
Q. Who is Dr. Burk?
A. Dr. Burk is an orthopedic surgeon who was an expert for Arthrex for the study.
Q. And what is your understanding of the test that Dr. Burk did?
A. He did a knot tiedown and a knot rundown test where he was comparing the coated -- the uncoated, unheated, unstretched with the coated, heated and stretched suture.
Q. And was he able to determine the difference between the samples?
A. Yes.
Q. How did he characterize the differences between the samples?
A. He characterized the differences as subtle.
Q. Were you able to determine the construction of the samples you said?
A. Yes.
Q. Now, the fact that you said that one sample was uncoated, unheated and unstretched, and the other was coated heated and stretched, and the differences he said were subtle, to your understanding, what does that mean?

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A. It tells me means that in the entirety of the coating, heating and stretching makes a subtle difference, so one, and that being the case, the heating -- consider it's heated and stretched, the coating would be even less than subtle.
Q. Okay. And did you consider and make that determination from the photo micrograph that you looked at yesterday?
A. Yes, I did.
Q. Were you able to see yesterday whether the peaks and valleys were affected by the heating and stretching?
A. Yes, they are.
Q. And is that based on your visualize analysis of what you looked at under the photo micrograph as well?
A. That and the fact that the diameter got smaller.
Q. Now, Plaintiff's Exhibit 619, please. Does Dr. Burk's testimony support -- how does Dr. Burk's testimony relate to your opinion as to whether FiberWire's coating has a material effect on the last box, novel-based characteristics in Plaintiff's Exhibit 619?
A. That there's no material effect on the pliability and handleability.
Q. Okay. So, based on all your analysis, were you able to make a determination of whether Fiberwire's coating has a material effect on the last known novel --
A. Yes, sir.
Q. And what is your opinion?

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A. It has no material effect.
Q. Okay. Could you check that box off, please.
A. Thank you.
Q. Could I have Exhibit 618, please. Exhibit 618 we were looking at yesterday, you checked off all the boxes, and based on your analysis, have you reached a conclusion as to whether FiberWire's coating -- I'm sorry, let me rephrase that question. Did you reach a conclusion as to whether FiberWire satisfies the "consisting essentially of" limitation of the claims?
A. Yes, I did.
Q. Could you please check that box off?
A. Yes.
Q. Your Honor, I'd like to move in some exhibits. I'd like to move in Exhibits 499, 500, 554, 553, 506.
THE COURT: Have you gone through them with the other side?
MR. BONELLA: Yes. There's no objection, I understand.
MR. SABER: The only one I had a question about, your Honor.
THE COURT: Which is the one you had a question about and we'll deal with it at sidebar later?
MR. SABER: Yes. 506.
MR. BONELLA: 499, 500 --

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Pearsalls' coating, heating, and stretching process?
A. Yes.
Q. Can you tell the jury, is the FiberWire suture stretched during that process?
A. Yes, it is.
Q. Did you ever say in your expert reports that it was not stretched?
A. I never said it was not stretched.
Q. Okay. And did you say in some of your expert reports that it was in fact stretched?
A. Yes, I did.
Q. Do you recall that Mr. Saber asked you about an Exhibit G to one of your expert reports?
A. Yes.
Q. And he didn't show that to you, I don't believe? He did show it to you?
A. I don't remember sitting here now.
Q. Can you look at Exhibit 501, please.
A. Yes, I can.
Q. Is that Exhibit G?
A. Yes, it is.
MR. SABER: Objection, your Honor. I just don't believe this is a -- the original one was in color, and this is not an appropriate --
MR. BONELLA: I don't think it was, but --

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MR. SABER: My recollection was --
THE COURT: Do you remember whether there was any coloring on it?
THE WITNESS: They're only done in black and white. It might have been on a color piece of paper, but they're done in black and white.
Q. Exhibit 501, is that Exhibit G to your expert report that he was asking about?
A. Yes, it is.
Q. Is that a twice-coated suture?
A. Yes, it is.
Q. That's a FiberWire suture?
A. Yes, it is.
Q. And did you analyze this with a photomicrograph?
A. Yes, I did.
Q. And were you able to see it clearly under the microscope when you were looking at it?
A. Yes.
Q. And did you see in this coated suture whether the heating and stretching had smoothed out any of the peaks and valleys?
MR. SABER: Objection, your Honor. Beyond the scope.
THE COURT: Overruled.
Q. Were you able to see whether there was coating on the

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inside when you actually looked, in addition to this picture, when you were looking under the microscope, whether there was coating inside the structure?
A. Yes. I could not see coating.
Q. Okay. And did you see whether the coating in Exhibit 501, whether it filled in the peaks and valleys on the FiberWire?
A. When I looked under the microscope, I did not see coating fill the peaks and valleys.
Q. Okay, thank you. Let me show you Exhibit 554. Can you bring up Exhibit 554, please. Do you recall this from your testimony yesterday?
A. Yes, I do.
Q. And was this the coated sample yesterday?
A. My recollection, it was coated, heated, and stretched twice.
Q. Right. And why did you choose to use this picture as opposed to the last picture?
A. Because the pictures came out a little clearer.
Q. Okay. Mr. Saber asked you about the angles and the way the pictures were. Did that affect your ability, when you were looking under the microscope and when you took the pictures and did the analyses, did it affect your ability to see where there was coating or whether there was coating?
A. Not at all.

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Q. Could I have Exhibit 279, please. Do you recognize Exhibit 279?
A. Yes, I do.
Q. Could you blow up the block that says "Stretching and Coating," please, Mr. Ficocello. What is Exhibit 279?
A. It's a manufacturing flow chart that was given to me when I visited Pearsalls in England.
Q. And what is the process that's described in the manufacturing flow chart from Pearsalls?
A. Stretching and coating.
Q. Did you use this analysis, use this in supporting your opinion that FiberWire suture is stretched?
A. Yes, I did.
Q. Could you bring up Exhibit 623, please. Let me just ask -- I'm sorry that's the wrong exhibit. 622, please. Mr. Saber asked you about the rollers and the configuration of rollers in your diagram?
A. Yes.
Q. Does that configuration matter to your opinion as to whether there was a stretching process?
A. Not at all.
Q. Does it matter to your opinion whether there was a heating process?
A. Not at all.
Q. Now, I'd like to turn to a little different subject.

EXHIBIT 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 683-904
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY SIX

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 14, 2007 9:03 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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or lack of frankness that the witness showed while testifying, the reasonableness or unreasonableness of the witness's testimony, the probability or improbability of that testimony, the opportunity or lack of opportunity that the witness had to see and know the facts about which he or she was testifying, the accuracy of the witness's recollection, the degree of intelligence shown by the witness, the witness's prior conduct for truthfulness, and whether the witness has attempted to fill in gaps in his memory of events with information he obtained after the event.

You may also consider whether the witness has a motive for testifying and the interest or lack of interest that the witness may have in the outcome of the case. You may take into consideration the character and the appearance of the witness at trial and any bias he's shown in his testimony. You should also consider whether the witness made prior inconsistent statements before trial in considering credibility. This list is not exhaustive. Rather, it is a list of factors you can consider.

You've also heard testimony from persons described as experts, so-called expert witness testimony. Persons who, by reason of skill, training, education or experience have become expert in some field may state their opinions on matters in that field and may also state the reasons for their opinion.

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Expert testimony should be considered just like any other testimony. You may accept or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the soundness of the reasons given for the opinion, the acceptability of the methods used, and all other evidence in the case.

Okay, now, that is what I would call the first portion of the jury charge, and I'm about to move on to the things that are very specific to this case, the middle portion of the charge.

As you know, the plaintiff in this case is DePuy Mitek. Sometimes the parties refer to it as Mitek. That's the plaintiff. The defendants in this case are Arthrex, Inc. and Pearsalls Limited. You have heard evidence regarding both defendants' involvement in the case, but for purposes of your deliberations, you should treat Arthrex and Pearsalls the same. And you'll see we've done that in the verdict slip, so you need not make distinctions between the two.

Now, what are the claims here? I'm going to give you a little bit of an overview. Plaintiff alleges that the defendants have infringed upon the claims of the '446 patent, which we've also called the Hunter patent, and that's the patent I handed out on the first day of trial. Defendants deny this allegation.

Deciding whether a claim has been infringed is a

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two-step process. The first step is to decide the meaning of the patent claim. I've already made this determination and will instruct you as to the meaning of the claim at issue here, and I showed you what that was on the patent. The second step is to decide whether defendants have made, used, sold, offered for sale, or imported within the United States a product covered by Claim 1 of the Hunter '446 patent. You, the jury, must make the determination about whether there's been an infringement, and that's what you're asked on the verdict form.

Now, the following claim terms -- and I'm once again referring back to Claim 1 in the patent that I handed out to all of you -- the following claim terms have the following meanings. You'll see in Claim 1 that there is the abbreviation PE. PE includes all polymers formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. You've sometimes seen that shortened as UHMWPE.

So let me say that again: PE as it is in Claim 1 includes all polymers formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene.

What do we mean by the "basic and novel properties" of the suture described in the Hunter '446 patent? You remember I handed that out to you on the very first day, and I hope you still have a copy of what I said it was so you

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don't have to write it down, but I'm going to read it to you right now. The "basic and novel properties" of the suture described in the Hunter '446 patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim 1, (3) where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture. You have that already in writing.

So to prevail on its claim, what does the plaintiff have to prove? To prevail on its claim, DePuy Mitek must prove by a preponderance of the evidence that defendants have made, used, offered for sale, sold, or imported into the United States the invention defined in Claim 1 of the Hunter patent.

A person can directly infringe a patent without knowing that what he is doing is an infringement of the patent. He may also infringe even though in good faith he believes that what he is doing is not an infringement of any patent.

Also, an accused product may infringe an asserted patent regardless of whether the accused infringer has its own later-issued patent on the accused product. In other words, the fact that Arthrex has a patent covering FiberWire

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does not constitute a defense to infringement of plaintiff's Hunter '446 patent.

So now I want to discuss a very unique patent term, which is the term "consisting essentially of." You've seen that a lot and heard a lot about it, "consisting essentially of."

I call your attention to a phrase used in the Hunter '446 patent, "consisting essentially of," which has a very special meaning in patent law. Here, the phrase "consisting essentially of" means that the claim may encompass FiberWire sutures that include ingredients that are not expressly listed in the claim, provided those ingredients do not materially affect the basic and novel properties of the invention, as I've just defined them.

I'll repeat that again. Here, the phrase "consisting essentially of" means that the claim may encompass FiberWire's sutures that include ingredients that are not expressly listed in the claim, provided those ingredients do not materially affect the basic and novel properties of the invention, as I have just defined them to you.

An effect on the basic and novel characteristics of an invention is material -- that's a legal term, "material." You've heard that term too. An effect on the basic and novel characteristics of an invention is material

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if the effect is of importance or of consequence to those of ordinary skill in the art.

Let me state it again: An effect on the basic and novel characteristics of an invention is material if the effect is of importance or of consequence to those of ordinary skill in the art.

The only question here before you is the effect of the silicone coating. The only question here is the effect of the silicone coating. You will need to consider the evidence and decide whether the silicone coating on FiberWire has a material effect on the basic and novel properties of the suture.

Again, you will need to consider the evidence and decide whether the silicone coating on the FiberWire suture has a material effect on the basic and novel properties of the suture.

Mitek claims it does not have a material or important effect, and Arthrex contends that it does have a material or important effect.

To say it another way, the FiberWire sutures do not infringe the claims of the Hunter '446 patent if the coating on the FiberWire sutures materially affects the basic and novel properties of the invention, as I have defined it. Ultimately, you will have to decide based upon the evidence whether plaintiff has proven that the coating included in the

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sutures sold by the defendants does not materially affect the basic and novel properties of the invention as I have just read them.

I'm going to read that paragraph again that started "to put it another way." To put it another way, the FiberWire sutures do not infringe the claims of the Hunter '446 patent if the coating on the FiberWire sutures materially affects the basic and novel properties of the invention, as I have defined it. Ultimately, you will have to decide based on the evidence you heard whether plaintiff has proven that the coating included on the FiberWire sutures sold by the defendants does not materially affect the basic and novel properties of the invention as I have just read them to you.

What do I mean by materially affecting? In determining whether the coating added to FiberWire materially affects the basic and novel properties of the invention, it does not matter whether you determine that the coating has an improving effect or a worsening effect on those properties. The only thing that matters in your analysis is whether the effect is material or important. Material means important. If you decide that the effect is not material, then you should find that FiberWire infringes. If you decide that the effect is important, then you should find no infringement.

In determining whether the coating added to

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FiberWire materially affects the basic and novel properties of the invention, you may consider the '446 patent, or the Hunter patent, concerning the effect of coatings. Actually, both sides rely on the patent to some extent. However, you must look at all the evidence in deciding the question of whether the coating added to FiberWire materially affects the basic and novel properties of the invention as I just read them to you.

I now move on to what I will call Part III, which is the mechanics of deliberation. The first thing that you should do when you go back into that jury room is to select a foreperson. I used to do that when I was a newer judge. I used to watch who took notes, who seemed to be paying attention and who seemed to be daydreaming, who came on time. But it soon became apparent to me that you all know each other a whole lot better than I would know any of you at this point. So, please, the first thing you do is go in and choose a foreperson.

But the foreperson is not more equal than the rest. You've heard, again, both sides say, "We're content with all the jurors." So all of you serve as equals in that room. Rather, the foreperson has certain obligations to me. First, the foreperson will fill in the verdict form. There will be one official verdict form. The foreperson will fill it in, sign it, date it, and certify that it's unanimous. It

EXHIBIT 9

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 523-682
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY FIVE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 13, 2007 9:04 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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(THE FOLLOWING OCCURRED AT SIDEBAR:)
MR. SABER: Your Honor, I'd like to move for a judgment as a matter of law, on several grounds including that Depuy Mitek hasn't established proper ownership of the patent. I understand your Honor has something to reserve?
THE COURT: I'm reserving on that one. You're preserving.
MR. SABER: They didn't put it in, no chain of title, et cetera. We don't believe this is just for the record, your Honor, that they've established that they meet the requirement of the claim of the first set of yarns because the ultra high molecular weight polyethylene is not any of the substances identified within the first set of yarns. I understand your Honor's claim construction.
THE COURT: Find, you need to preserve it.
MR. SABER: We object to that. We also believe they've not met their burden that the coating is not of a material of the basic and novel characteristics. Among other reasons, they haven't put in evidence which establishes that there's a material effect on suture, handleability and pliability. We don't believe they've put in evidence that the coating does not sacrifice physical characteristics, properties of the constituent elements. I don't have your exact words.
THE COURT: Doesn't meet the claim construction.

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MR. SABER: That's right. We also believe that the evidence they put in through Dr. Brookstein shouldn't be considered because we don't believe that the record shows that he's qualified to issue opinions and that he didn't have the proper basis for his opinions, and with respect to Dr. Burk's, he got the samples right and the evidence was subtlety of differences doesn't go to the fact of what you need to prove, it's not a material difference.
THE COURT: Denied for ownership which I'm reserving. I'm assuming a bunch of those exhibits that you put in at the last minute were ownership?
MR. SABER: I think three of them were.
THE COURT: I don't want to put those before the jury. It will be too confusing.
MS. ELDERKIN: I understand that.
(SIDEBAR CONFERENCE WAS CONCLUDED)
THE COURT: Next up at bat.
MR. SABER: Your Honor, the defendants call Lawson Lyon.
LAWSON LYON, having been duly sworn by the Clerk, testified as follows:
THE CLERK: Would you please state your name and spell it for the record.
THE WITNESS: Yes, my name is Lawson Lyon, L-a-w-s-o-n L-y-o-n.

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DIRECT EXAMINATION
BY MR. SABER:
Q. Good morning, Mr. Lyon.
A. Good morning.
MR. SABER: Good morning, your Honor; good morning, ladies and gentlemen of the jury, I hope you all had a nice weekend.
Q. Mr. Lyon, I know you've been sitting here patiently all last week, and now is your opportunity to talk a bit to the jury. Could you tell the jury where you're from?
A. Yes, I live in Devonshire, England.
Q. Who do you work for?
A. Pearsalls Limited.
Q. Okay. Where is Pearsalls Limited located?
A. It's in Taunton, Somerset.
Q. That's also in England?
A. Yes, sir.
Q. What is your position with Pearsalls?
A. I'm the managing director.
Q. And could you explain for we Americans what a managing director means?
A. Well, I think your equivalent would be the CEO so I'm responsible for the overall running of the business. I take particular interest in the sales and marketing side, the quality, particularly, and the product development.

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Q. Are you involved in the manufacturing side as well?
A. Oh, yes.
Q. Could you explain briefly to the jury what your involvement is I think on some of these things I'd like to ask about on product development what you're involved with that?
A. Well, product development emanates from the customers, so I'm the one that visits the customers, and that's where most of the ideas that go into product development come from, and then I monitor the progress of the development as it carries through.
Q. Do you get involved in the actual development of products at times?
A. Oh, yes.
Q. And you mentioned quality. What is your involvement that you have with quality? What do you mean when you say quality, first of all, so the jury understands?
A. We manufacture materials that are highly critical components in medical devices, so the quality has got to be good, and we have a registration for the NIS 1,000 which is a general quality standard. We also have registration to ISO 13485 which means we can make medical devices. We're registered with the FDA, so those issues I take a great interest.
Q. Could you explain what your involvement is with the

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fishing line, which is a lot stronger than any other fishing line on the market, and we had also done some previous experiments to make a suture.
Q. Could you tell what you did next in the development of FiberWire?
A. Yes, we prepared some prototypes, the first ones, first of all, we did 100 percent polyester, one just to see how it performed, then we went to 100 percent ultra high molecular weight polyethylene. Those were the very first two ones we did.
Q. What happened to those?
A. Well, we were hoping that the ultra high molecular weight polyethylene would be satisfactory, but we got a report back immediately that, yes, it was a lot stronger but the knot security was not satisfactory.
Q. And what happened next?
A. Well, then we then moved on to testing, the idea that we mixed the ultra high molecular weight polyethylene with polyester, with PET in the cover, which is what we do in our fishing line, then the knot security might be better.
Q. Okay. Now, and ultimately was there a product that came out that mixed the ultra high molecular weight polyethylene with the polyester?
A. That's what happened, yes.
Q. Is FiberWire coated, sir?

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A. Yes, it is.
Q. Could you explain how it was decided to coat FiberWire, your involvement in that, sir?
A. Well, pretty soon after we established that the mixture of the two materials would give us the knot security, then we said we'd go to various things we've got to do before this can be a suture, and one of them that it has to have a coating.
Q. Were you part of that decision on having to have a coating?
A. Oh, yes.
Q. Why did you believe it needed to have a coating?
A. Well, because a braid without a coating does not give you a good knot run-down and the surgeons would not be happy to have a suture like that.
Q. And so did you suggest a specific coating to use?
A. Yes, I did.
Q. And what coating did you suggest?
A. This was the Nusil 2174.
Q. And that suggestion came from you, sir?
A. Yes.
Q. And when you described why you suggested the coating, does FiberWire coating meet those goals?
A. Yes, it does.
Q. Okay. Now, you identified Nusil 2174. What kind of

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coating is that?
A. Well, it's a silicone rubber base, and I want to get through the process how you actually put on, but it's a silicone rubber that's cured onto the surface of the braid.
Q. Why did you suggest that particular coating, sir?
A. Well, we've been using that particular one for a couple of years which meant that we've already established with the FDA firstly, and, secondly, it appeared to us to be a very good coating for fulfilling the needs.
Q. Was that based on your experience with other products?
MS. MALINOSKI: Objection.
A. Yes.
Q. Did Arthrex --
THE COURT: You know, this isn't working, so if you object, you have to stand up and speak in a nice and loud voice. I didn't even hear that, and we went right through. If it doesn't happen, you all have to stop because I can't rule that fast. You are leading a lot, so you need not to lead, and that will eliminate most of her objections.
Q. Mr. Lyon, do you understand if Ms. Malinoski stands up to object --
THE COURT: You got to do it assertively so that's how we'll work it.

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Q. Okay. Did Arthrex accept your recommendation to use the Nusil coating?
A. Yes, they did.
Q. Now, is there a patent that covers the work that came out of the FiberWire project?
A. Yes.
MS. MALINOSKI: Objection, your Honor.
THE COURT: Overruled.
Q. Are you an inventor on that patent?
A. Yes, I am.
Q. If you could look in your book at Exhibit 1133. What is Exhibit 1133?
A. It's the United States Patent No. 6,716,234B2.
Q. And what is this?
A. It's a patent for a high strength suture material.
Q. Is this the patent for the FiberWire project?
A. Yes, sir.
Q. And are you identified as one of the inventors on that?
A. Yes, I am.
MR. SABER: Your Honor, I move to admit Exhibit 1133.
MS. MALINOSKI: No objection, your Honor.
THE COURT: All right.
(United States patent No. 6,716,234B2 was marked

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and admitted into evidence as Defendant's Exhibit No. 1133.)
Q. In this patent that you're an inventor on, do you make any statements in this patent as to why coating is added to FiberWire?
MS. MALINOSKI: Objection, leading.
A. Yes, I do.
THE COURT: Overruled.
Q. Could you identify where in the patent that is?
A. It's in example 2.
Q. Okay. Is that the second column? It might be a little bit easier if you could identify the lines and the numbers so Derek can put it up on the board.
A. It's in column No. 2 in example 2, third paragraph which is line 48.
Q. Could you read to the jury what your patent says about why coating was added to FiberWire?
A. Yes, the suture is preferably coated with a silicone-based coating to fill in voids and provide optimum run-down.
Q. Thank you. Let me now turn to the process that Pearsalls uses to apply the coating to FiberWire. Were you involved in the development of that process?
A. Yes, I was.
Q. Could you -- we've developed, put an animation on this to perhaps help Mr. Lyon's testimony.

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MR. SABER: Could you put up Exhibit 1354, Derek.
Q. What is this, Mr. Lyon?
A. This is a diagram of our coating process.
Q. Okay. Could you perhaps just run it first and then we'll go back and have Mr. Lyon explain a bit. Can you keep it up, please, Derek. Could you put the words on so if I ask any questions. Well, let's start here. Let's start at the left-hand side where it says spools of uncoated FiberWire. What does that show?
A. That's showing a number of spools of FiberWire. I think the batch size for FiberWire is about 18 spools.
Q. Okay. And what happens as -- what's the next step after it comes off the spool?
A. It's taken off the spools there that are on that creelcreel and it's taken down into the tank.
Q. And that's where it says heating tank with coating solution?
A. Heated tank with coating solution, that's correct.
MR. SABER: Derek, could you put up the other words that describe the heated tank with coating solution.
Q. Could you explain how that heating tank works.
A. Well, it's containing the solution. Do you want me to say --
Q. Yes, could you explain the things in the solution.
A. It says there it's got the Nusil silicone, solvent to

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make it into a solution, a bonding accelerator.
Q. I'd like to stop you right there and ask you this. What is the Nusil silicone?
A. It's a silicone rubber. It arrives at us in a solid form, solid lump of rubber, and they then chop it up into small pieces and we mix it with a solvent in a great big mixing bowl.
Q. Why do you mix it with the solvent?
A. To make it into a solution, to make it into a liquid so we can immerse the braid into it.
Q. And the next thing you have -- what is the solvent?
MR. SABER: Please keep those words up.
A. The solvent is Xylene, a pretty standard solvent.
Q. And the next thing you say is the bonding accelerator?
A. Yes.
Q. What is that?
A. The trade name for it is lubricol, and it is a benzoyl peroxide.
Q. And what is the purpose of the bonding accelerator?
A. So, as it goes through the heating oven, it is an activity that cross-links the silicone to each other and bonds it onto the material, onto the braid.
Q. And what role does the bonding accelerator play in that?
A. I think what it does is it actually achieves the cross linking of the silicone rubber.

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Q. Do you know why the word "accelerator" is used?
A. To do it quicker.
THE COURT: Let me ask you, do you know?
THE WITNESS: These are chemical phrases. I'm not actually a chemical expert.
THE COURT: He's not an expert on this.
MR. SABER: He's the one that developed this, your Honor.
THE COURT: He just said he didn't know.
Q. Now, are you familiar with why these steps are in the process?
A. Yes.
Q. Okay. Now, the next thing that's said there it says it's heated to 26.5 degrees Celsius?
THE COURT: Do you know?
THE WITNESS: I'm looking to see which one he's talking about.
Q. The next line down?
A. That's the solution in the tank, yes, that's so the viscosity of the solution can remain constant by keeping it as constant here.
Q. The next thing you say is about the viscosity. Is the viscosity checked every 15 minutes?
A. Yes, it is.
Q. Why is that?

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MS. MALINOSKI: Objection.
THE COURT: Do you know?
THE WITNESS: Yes, I do.
THE COURT: Just make sure.
A. I know if you've got a solvent, it evaporates in the air and the solvent in this tank will evaporate so we need to maintain a constant viscosity because the solvent is continuing to evaporate, so if at the 15-minute stage we test it and it's below the viscosity, it's thicker, we add more solvent.
Q. What is the next thing that happens after it comes out of the vat?
A. Well, it goes through these pads, they're called wiper pads, and what they do is they squeeze off the excess coating solution.
Q. Why is excess coat coating solution squeezed off?
A. We don't want too much of it, otherwise it would be too much to dry off to evaporate the solvent and it probably is too much for it to be bonded, fully bonded.
Q. Now, after the pads, there are two little gray things there?
A. Yes.
Q. What are those?
A. Those are stretching rollers.
Q. Are those used in the FiberWire process?

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A. No, they're not.
Q. Now, what's the next part of the process?
A. Well, it goes through these ovens at a set speed, 20 meters per minute. There are four separately controlled ovens. You'll see there the first two 100 degrees second grade, then it goes up to 130, then 170.
Q. Now, why does it go through the ovens?
A. It goes through the ovens to evaporate the solvent and to bond the coating. Cure the coating is another phrase that's used.
Q. That's sometimes used for that?
A. Yes.
Q. And the third thing is it dries the coating. What is that referring to?
A. Well, that means evaporates the solvent and therefore dries it.
Q. Okay. After it goes through the oven, what happens next?
A. It's pulled through the oven by those two rollers on the end, and then from those rollers, it goes to the uptake creel and to the uptake rollers that are in the creel.
Q. Then what's the next step?
A. We stop and go over it again.
Q. We don't have to go through it again. It's the same process the second time?

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A. Yes, sir.
Q. Why do you go through the process the second time?
A. Well, when we were talking about it, we said that we could have one coating or two coatings. We've validated both. I remember discussing it with Mr. Grafton. He said well, which --
MS. MALINOSKI: Objection, your Honor.
THE COURT: Sustained.
Q. If you could just tell them why you do the two coatings.
A. Well, we felt it would fit in any voids in the braid better than if we did one.
Q. Now, when did Pearsalls start using silicone coating for its sutures?
A. 1986.
Q. Were you personally involved in that process?
A. Yes, I was.
Q. Could you explain what your involvement was in 1986?
A. The second biggest suture company in the world, Davis & Geck came to us and said --
MS. MALINOSKI: Objection, your Honor.
THE COURT: Sustained. You know, the basic concept is you can't tell us what somebody else said. That's hearsay.
THE WITNESS: All right. Even if he said it to me?

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THE COURT: That's the basic rule I follow.
THE WITNESS: Right.
A. Anyway, what they would do is braids were very satisfactory, but we needed to improve our coatings, and they would assist us in doing that.
Q. What did Pearsalls do? What did you do?
MS. MALINOSKI: Objection, your Honor.
THE COURT: Overruled.
Q. What did you do?
A. They gave us a specification for a coating process. We went down and bought a coating sheen, and we established it and commissioned, and they came over to us to assist in the development of this coating.
Q. Could you briefly describe the process that you went through as you developed your coating process?
A. We did, first of all, we had to make the solution properly, so that took a while, developed how the viscosity should be and how we should test for that, and then we also experimented with speed, speed through the oven, and we experimented with different temperatures of the oven.
Q. And about how long did this process take to --
A. About six months, I would say.
Q. Just let me finish my question. To install this coating process at Pearsalls?
A. Six months.

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Q. Now, as Pearsalls was developing the coating process, were there any other steps that Pearsalls took to ensure that the coating was done properly?
A. Indeed. The other thing they taught us was how to test for it, which was how to do, how to test for it using run-downs and how to do that more scientifically than just doing one run-down.
Q. And were you involved in those tests?
A. Yes.
Q. Could you explain what that involvement was?
A. Well, what we would do after we made a number of different prototypes on the machine, we sit down in the evening, they'd all be marked up, we'd have a panel of about six people, we'd have a standard that we were trying to work to so we would do some run-downs on the standard, and then we'll take the individual prototypes that we've made and we'd each test these and mark them as to how we consider the run-down was working, and the important thing with each one had to be run-down 10 times to make sure that the run-down, the friction hadn't changed.
Q. Now, has Pearsalls been using this coating process that you've described for FiberWire continuously since 1986?
A. Yes.
Q. Now, looking back at the animation here, are these parts that you've described, the bath, the wiper pads and the

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oven, is that all part of the coating process?
A. Yes, it is.
Q. Could FiberWire be coated if it just went through the coating bath?
MS. MALINOSKI: Objection.
A. It would pick up too much coating.
Q. Was that a yes or no?
A. No.
Q. And could you explain why?
A. Well, A, would pick up too much coating, and, B, it hadn't gone through the oven, that's the other part.
Q. And why is the oven a vital part of it?
A. Because it cures the silicone rubber and evaporates the solvent.
Q. Now, turning specifically to FiberWire, what steps do you take to make sure that the coating is properly applied?
A. Well, we can't do a test to say how much coating is on it because you cannot take the coating off, not in a simple way that we would like to have, so the most important thing is to control the process, and the process is very tightly controlled by the viscosity readings over 15 minutes by taking a sample of the solution for each run and checking there is a certain percentage of silicone in solution. We do that for every run, and we keep very accurate records of

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what we've done.
Q. Are there any other physical checks of the suture itself that Pearsalls goes through?
A. Not for production.
Q. Is there any other check after the coating to make sure it's done right?
A. After this process is initially passed by quality control, it goes to what's called inspection, and inspection entails running the suture braid through an inspector's fingers as it's being run on the wheel.
Q. Were you involved in doing that process?
A. Oh, yes.
Q. What was involved?
A. The lady monitors as it's going through her fingers, and if she finds any defects in the braid, she'll stop the process, cut out the defect, make a note, record what the quality defect was and then record on the wheel how many knots there are on the wheel.
Q. Are there any occasions where the FiberWire has to be run through the oven again?
A. Not --
MS. MALINOSKI: Objection, leading.
THE COURT: Overruled. When she objects I just need to think about it for a second so you got to listen in the back of your mind so the objection is overruled but you

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just have to wait.
Q. Go ahead.
THE COURT: I think that's how it works in British courts, too, we got it from them.
A. Would you mind repeating the question?
Q. Sure. Are there occasions where the suture has to go through the oven again?
A. No, not as a standard process.
Q. As a nonstandard process?
A. It's possible if the coating hasn't been properly cured that it would be put through the oven again.
Q. How do you know if it's not properly cured?
A. There might be some little white specks on it.
Q. What happens if you find the white specks?
A. We put it through again.
Q. Now, you were sitting here to hear Dr. Brookstein testify that the FiberWire goes through a stretching process?
A. Yes, I did.
Q. Is that correct?
A. No, it's not.
Q. Now, could you quickly look at Exhibit 279, and did you hear when Dr. Brookstein made reference to where it says stretching and coating on that document?
A. Yes.

EXHIBIT 10

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 683-904
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY SIX

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 14, 2007 9:03 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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Dyneema to the field of development as well as look to some other ways to improve. At that time came the coating, and the coating actually has to be absorbable. You cannot use silicone or any other things, so it was a proprietary material synthesized in the American Cyanamid lab in Stanford, Connecticut, and the coating process was developed, and that's another thing, we initially went through three percent coating level, then we got a complaint that knocks everything up, so we had to reduce the coating level to at most five percent.

After that then I was promoted to group leader of the extrusion and biomaterials, and at that time the civil engineers, professors, suture professors reported to me, and one of them was in the braiding and the coating, and this fellow has 25 years experience in braiding, coating, silk, Ticron, so forth. I didn't have to do any research and development.

Then during that time frame -- I forgot to mention this -- the most important part of my life was I developed Maxon absorbable multifilament suture, and I'm very proud of that development because it makes millions of dollars now, and if I may say so a little bit of personal experience that I took a Maxon suture to take to my mother that was very sick, and they used it on my mother. That's the kind of thing I did, and from the polymers to the extrusion to the

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suture introduction, I did all of this, and I still give a lot of interest what surgeon is using Maxon, which surgeon is not.

Then I was promoted to staff physician technical specialist of biomaterials. At that time we also didn't have the market, and that's where I developed a shoulder tack. This is before the suture anchors came, so and I did that with Dr. Russ Warren. You may know him. He was the staff physician for the Giants football team, so we developed that and marketed it.

Q. During the 13 years you were at Davis & Geck, did you spend -- what percentage of time did you spend working on sutures?

A. Well, most of the time, I mean, I can't say percentages.

Q. Just to give the jury an idea.

A. 80 to 90 percent, very little in the new products, they're like an orthopedic suture that I talked about.

Q. Now, while you were at Davis & Geck, did you actually see the coating machines in operation?

A. Oh, many times.

Q. And have you also been involved -- I think you mentioned something about testing sutures. Could you briefly explain what your involvement is in testing sutures?

A. Yes, during extrusion or any other time, I always

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involved in the suture testing. I know how to run an instrument, still I do in my lab, so we wanted to see the strength pull, knot pull, personal observation. We also have some specialized tests looking at the tissue drag, those kind of things.

Q. Dr. Mukherjee, I'd ask you if you could just slow down a little bit on your answers because it might help the reporter get it down.

A. I'm sorry.

Q. No problem. I think we all sometimes suffer from that. Do you have expertise in analyzing test results?

A. Yes, all the time.

Q. Let me move on, I think the jury hopefully has got a pretty good idea who you are and what you've done. Let me ask you a little bit about now move to this case, if I could. Could you explain generally to the jury what you were asked to do in this case.

A. I was asked to take a look at the '446 patent and Arthrex's FiberWire suture, and I was asked does FiberWire product infringe into the '446 patent.

Q. Okay. Were you asked to do anything specifically with respect to the coating issues?

A. Yes.

Q. Could you tell us?

A. Does the coating change in basic and novel

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characteristics without affecting the field properties such as knot security?

MR. SABER: Okay. Could you put Exhibit 632 up on the board, please. 632 is the claim construction that the jury, that's been given to the jury by the court.

Q. In your opinions, have you analyzed the effective coating on what is listed as the basic and novel characteristics given by the Court?

A. Yes.

Q. Okay. Now, is there a specific part of this that you concentrated on?

A. I concentrated on pliability and handleability.

Q. Is that item No. 4 that's there?

A. Yes.

Q. Okay. Now, I assume you're being paid for your work you've done in this case?

A. Yes.

Q. Okay. Could you tell the jury about how much you're getting paid?

A. I'm paid $1,000 a day. I also work on an hourly basis, $150 an hour.

Q. Okay. Now, could you just tell us the kinds of things that you did to help you render your opinions in this case?

A. First of all, I got familiarity with the issues. I

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spoke to the, you know, the law firm to get that idea, then I looked at the literature from the Ethicon Depuy Mitek papers and several other authored documents, Depuy documents. I could list all of them.
Q. I'm not asking you to. I'm just trying to get a general idea of the things you did. Did you review any test results?
A. Yes. I actually got involved in the testing and planning phase with Dr. Gitis, and I reviewed his results, and then I was told about some surgeon relation, but I decided not to get into that, and that's why on the deposition I didn't ask for Dr. Burk's deposition.
Q. Okay. Did you review his test report that he had done prior to his deposition?
A. Yes, I did.
Q. Okay. Is that referenced in your report?
A. Yes.
Q. Okay. And did you use your years of experience that you described to the jury in rendering your opinions?
A. Absolutely. I'm more than 30 years of experience. I live with sutures, I smell sutures, that's what I do.
Q. Dr. Burk, who actually uses the suture products, who's the ultimate end user?
A. It's the surgeons.
Q. Now, is it important as the suture manufacturer to

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understand the needs of surgeons?
A. Absolutely. We always, even for the early part of the development phase, when we were making polymers, we always speak to surgeons.
Q. And why do you do that?
A. Because they're the customer. Like you develop something, whether it's a toy or a fabric or whatever, you look at who is using it and what the requirements are, and you try to satisfy those on met needs.
Q. Now, did you come to an opinion as to whether the coating on FiberWire affects the basic and novel characteristics of the '446 patent?
A. The coating -- what is your question again?
Q. Did you come to an opinion as to whether the coating on FiberWire affects the basic and novel characteristics that you see in the claim construction?
A. Yes, I did.
Q. What is your opinion?
A. That it does affect the basic and novel characteristics.
Q. Is that a material effect in your opinion?
A. It's a material effect.
Q. Now, when you rendered your opinions on this matter, did you render it from the position of one of ordinary skill in the art?

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A. Absolutely.
Q. Could you explain what is the ordinary skill in the art here?
A. My experience, I hire a lot of people in the suture industry. They should have a science and engineering degree, about two to three years experience working in the suture company.
Q. Now, you see in the claim construction there's a term called "handleability" and term "pliability." Could you explain what that means?
A. Yes, sir.
Q. Sure.
A. Pliability is -- I'll give you a very simple example. If you take a small steel rod and you bend it, it's very stiff, but if you take a straw that you drink your soda, you bend it very easy, and that's pliability.
Q. How about handleability?
A. Handleability is a mixture of many things, but the first thing is the feel. And the suture, you give it to a surgeon's hands, how is the tactile feeling, then comes how does he tie the knot, what happens when the one strand goes with the other and then whether the knot is secure or not. All these things go in to handleability.
Q. Okay. How about as the suture is being used going through tissue, is that part of handleability?

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A. Absolutely, absolutely.
Q. Okay. Now, I know we've had a lot of terms thrown around in this case, and I don't want to take long. I think the jury's start to get at, so perhaps if I could ask you a few of the terms you made, if you could just explain them to the jury. I think you talked about, just mentioned that a suture running down -- the knot running down the suture. What is that called, and can you explain that to the jury?
A. Knot run-down, this is one term used that when you -- especially when you do the arthroscopic knot, you tie the knot at the top, and the knot has to slide all the way down. That's the knot run-down.
Q. Okay. And how about the word, "chatter." You've heard that in this case. Could you explain what that is?
A. Yes. Chatter is whenever there is friction that it produces a lot of resistance, there's a measure of how rough the surface is.
Q. And I think suture slide, is that the same thing as the knot? What is suture slide?
A. Well, suture slide is a lot of different things because when you take one up strand and it goes with the other, it's a very important property. In fact, I learned, if I may say so, maybe I take a little bit of time, when I was developing polyethylene suture, the suture was breaking, and our straight pull and knot pull is much higher than our

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competitor Ethicon, so I asked the product manager, show me how, why is the suture breaking because our measurements show that it's much stronger. Then he showed me what is going on. He take the one strand going with the other, when you tie the knot, and polypropylene is known for fibrillation, so it picks up the small fibers, and it breaks, so the surface, how the suture is stranded one over the other slide is very important property, by the way.
Q. Now, we've heard the term, "tissue drag." Could you just give a moment on tissue drag?
A. That is after let's say you succeed, suture is not rough, you can tie the knot, but, ultimately, proof of the pudding that it has to go through the tissue. Basically the function of the suture is to stick to the tissue, so if it is too stiff and too much resistance, the surgeons will not use it, so tissue drag resistance should be very low.
Q. Okay. Now, this case, of course, is about braided sutures, as I think we all know by now. Are there handleability problems that arise with braided sutures?
A. Absolutely.
Q. Could you explain what those are?
A. These are the like at first, give you an example of your uncoated, that when you tie the knot, it gets stuck and it does not slip all the way.
Q. Let me just ask you, is Dexon a braided suture?

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A. Yes, I'm sorry, I should have said that. It's a braided suture, and the ease of tieing the knot is not there in an uncoated braided suture.
Q. And in your experience, how were these handleability -- are those handleability problems solved with braided sutures?
A. The only way that I know is put a coating on it. And most of the braided sutures, even today, they have coating if they are sold in the market. You can develop uncoated but don't do any good.
Q. Okay. I have a little animation here to talk about some of the things you've talked about knot run-down and the difference between coated and uncoated.
MR. SABER: Could you put up 1355, please.
Q. You may have a picture of it in your book.
A. Yes, I have it.
Q. Could you explain what this is, Dr. Mukherjee?
A. This is, you know, you are tieing the knot and you're pulling the two, what do you call it, eye of the sutures, two ends, and you pull it and you see how the knot travels all the way.
Q. Okay. We're going to show it kind of running here. Could you explain what the words that came up and what those, how that relates to an uncoated braided suture and with the knot run-down?

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A. The uncoated, as I said, it will chatter. It goes and stops, goes and stops. That's the way you see the chatter. It's slower to use and a difficult knot to slide, and, moreover, the greater force to maintain, greater force to start. All the way it produces a lot of resistance for the surgeon.
Q. Now, I see the word, "slower to use." What is that referring to?
A. It's slower to get the knot where you want to put it in because, you know, the word we use, stick slip, it slips and sticks, that's the kind of thing that slows down the use of the suture.
Q. Could you turn to Exhibit 1356, which is the next animation.
MR. SABER; derek, why don't you run it first then we'll let Dr. Mukherjee explain. Could you do it again, please.
Q. Now, first let me ask you, we've shown you a couple animations. Are these exactly accurate?
A. Yes, close to, yes.
Q. This is just -- is this a depiction of what's going on, it's not the exact thing?
A. It's as close as you can get.
Q. Okay. Now, could you explain what's going on in this animation?

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A. Okay. This is a coated braided suture. First of all, less chatter, not much of friction, and it's quicker to use because when you tie the knot, it goes, slides easily, doesn't feel that resistance and less force to maintain and less force to start. All of these are very important for a surgeon because he doesn't have time to fool around with the suture. His main mind is doing the surgery.
Q. Now, I want to talk a couple on the tissue drag and show a couple animations for you on that.
MR. SABER: Could you turn to animation 1362, please. I'm sorry, I might have given you the wrong. That one is 1363 on mine. I want the one for the uncoated one, Derek. The numbers got transposed, okay. Why don't you run it and we'll show what's going on here.
Q. Now, Dr. Mukherjee, could you explain what we saw on this tissue drag for uncoated braided suture?
A. This is another way of showing how difficult for the suture to go through the tissue even though the needle has made the hole, but because of these, this has been animated to show this like a saw that in order to produce through the tissue, you have to cut through the tissue, so it produces the damage plus, again, the surgeon really has to put effort to get the suture through the tissue. That's tissue drag.
Q. Now, you see the words, "sawing effect." Is that a term that's known in this art?

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A. Yes.
Q. Could you explain what that is?
A. That's like, again, you know, again when you cut something, you feel, it goes and then stops, goes and then stops. That's the sawing effect. The surgeons always --
Q. Could you turn to I guess it would be 1362 in yours. Why don't we show this animation. Dr. Mukherjee, could you explain what this is?
This is a coated braided suture, and it requires less force because there's no roughness on the surface, and it allows a small incision. By the way, you have for different applications like if you do a plastic surgery or microvascular surgery, they're very, very small needles that are used, and this is a very important thing, small incision. There's less damage to the tissue and minimal injury to the tissue, and that's the whole thrust behind the suture, this whole arthroscopy is that that reduces the size of the incision. By the way, you may know this, arthroscopy was discovered here in Boston by our X, what do you call it, he was from India, Dr. Patel.
Q. Now, I think as you know we've had testimony in this case, the coating that's on FiberWire is silicone coating. Are you familiar with silicone coatings?
A. Absolutely.
Q. Could you explain how you've become familiar -- what is

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silicone coating?
A. Silk is one of the oldest sutures, and I did some digging one time and, again, it's made in India because the suture was actually used in India 500 or 600 BC, and they called it sutra. Sutra, it was like a thread. They used to use horse's hair, then came silk, and Egyptians, they started using the inner lining of the sheep, and that's where the name Sutra came from, and if you forget everything but you will remember --
Q. I'm sorry, Dr. Mukherjee, we're a little short on time.
A. Okay, I'm sorry.
THE COURT: Actually it's really interesting, but we're really trying to get this going.
Q. I'll talk to you afterwards, I'd like to learn a little more about it. Could you really -- I was asking you about the silicone.
A. Okay. Even silk, all right, is so nice and everything but still braided silk is coated, and silicone being the most unreactive and readily available was the coating of choice, so that's why silicone coating came for silk, came for Ticron, PET, and whatever use you need nonabsorbable coating, you use silicone. The other alternative, you may be thinking of Teflon. Why not Teflon? Teflon flakes up. You might have seen on pots and pans how Teflon coating comes off.

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Q. Now, was silicone used by Davis & Geck on braided sutures?
A. Yes, sir.
Q. Now, have you reviewed the patent literature as to how it relates to why coatings are on sutures?
A. Yes.
Q. Okay. And let me just go through a couple of those, if I may. We're not going to go through them all. Could you put up Exhibit 1100, please. Do you know what this is? Is this one of the patents that you reviewed?
A. Oh, yeah. He's a good friend of mine.
Q. Which one?
A. Bezwada.
Q. Let me ask you about the second guy, Alastair Hunter, do you know who he is?
A. I don't remember, but I used to know a lot of different people at that time.
Q. Do you know whether Mr. Hunter is the same inventor that's on the '446 patent?
A. Yes.
Q. Who's the assignee of this patent?
A. Assignee is Ethicon, Somerville, New Jersey.
Q. Let's turn to column 1. I want to draw your attention to the language. Could you read the highlighted portion?
A. "Surgery sutures often require a surface coating to

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improve one or more of their performance properties. For example, multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture, so it passes easily and smoothly through tissue during operative procedures."
Q. Is this passage typical of the general understanding of what coatings do for sutures?
MS. ELDERKIN: Objection. Leading.
THE COURT: Overruled.
A. It does.
Q. Now, in your opinion is your opinion as you read this, is this passage talking about using coating on a specific suture, or is it a more generalized teaching of using coating on sutures?
A. No, sir. It's for general specific, it's not a specific one.
Q. Is it limited to any specific type of coatings, this teaching?
A. It does not.
Q. Let me move to the next one briefly. Could you move to 1101. Is this also one of the patents that you looked at?
A. Yes, sir.
Q. And is Ethicon also the assignee of this patent?
A. Yes.
Q. Okay. Could you turn to column 1. And is the

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highlighted portion -- I don't want to take the time -- is that basically the same language as we saw before?
A. Yes, sir.
Q. And what is your understanding of what this is teaching?
A. It's for general suture coating. It does better on tissue drag on operative procedures.
Q. Let's move to Exhibit 1102, if I can. What is that?
A. Dry coating of surgical filament patents.
Q. Is this one of the patents you looked at?
A. Yes.
Q. Who's the assignee of this?
A. Ethicon.
Q. Could you turn to column 1. And about the part that's highlighted, can you read that, please?
A. "Such multifilament sutures exhibit a certain degree of undesirable roughness or grabbiness in what has been termed their tiedown performance, that is the ease or difficulty of sliding a knot down the suture into place, or the ease of snugging a square knot in place."
Q. What is your understanding of what's being taught in this passage?
A. This is for any suture, any braided suture, you have that undesirable roughness and the tiedown performance difficulty of sliding a knot that we've been talking

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about.
Q. This is consistent with what you've told the jury today?
A. Yes.
Q. Now, I just wanted to go down to the very bottom of that page. The top of the next column, what is being -- does this -- why don't you read it, that's the easy way.
A. "U.S. Patent No. 3,297,033 discloses that the synthetic absorbable sutures described therein may be coated with conventional suture coating materials such as a silicone or beeswax in order to modify the handling."
Q. Okay. Now, what is your understanding as to what this is teaching about using silicone coating for these purposes?
A. This is to improve the knot tiedown and surface smoothness, to improve the surface smoothness.
Q. Is this typical of the teachings in the art as to why silicone coating is used on braided sutures?
A. Yes.
Q. Now, what you read there talks about absorbable sutures; is that correct?
A. Yes.
Q. Okay. Is it -- do you have an understanding of whether silicone coating is used on nonabsorbable sutures for these purposes as well?

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A. In fact, that's what it's used most, not absorbable sutures.
Q. It's usually used?
A. Yes, because silicone is nonabsorbable so they don't put absorbable sutures on a nonabsorbable coating.
Q. Okay, thank you. Now, did you review documents and testimony from Ethicon and Depuy Mitek in this case?
A. Yes, sir.
Q. Okay. I'm not going to take the time to put that stuff up now, but could you just generally tell the jury what you learned from your review of the Ethicon and Depuy Mitek documents and testimony.
A. If my memory serves right that the coating improves the performance of these braided sutures.
Q. Okay. In what kinds of performances?
A. Knot tiedown, tissue drag, all the properties, handleability, pliability that we talked about.
Q. Did it come as any surprise to you to see such statements made by the Ethicon Depuy Mitek witnesses and documents?
A. No, sir.
Q. And could you explain why?
A. Because that's generally accepted in the field.
Q. Okay. Now, let me turn to some discussion about FiberWire, in particular, if I could. As you know, I think

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one thing that everybody agrees on that FiberWire has a silicone coating. Do you have any reason to believe that the coating on FiberWire, that its use is any different than what you just described to us as general teachings in the field?
A. No, sir.
Q. Okay. Could you tell, generally, the jury why you have that opinion?
A. Because my experience of more than 30 years, and I'm quite familiar with the suture performance properties, all those things plus the literature, that's what I based on my opinion.
Q. Now, have you seen any statements by Arthrex as to why or by Pearsalls as to why they use the coating?
A. Yes.
MR. SABER: Could you put 1106 up on the board, up on the screen, please.
Q. Is this one of the documents that you reviewed?
A. Absolutely.
Q. Okay. Could you identify what this is?
A. This is a product information FiberWire information from Arthrex.
Q. Could you read the highlighted portion, please.
A. "The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgery use. The

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Q. If you can, the last two columns, the T threshold and the experimental T value, I think that's what you're referring to?
A. Yeah.
Q. If you could try and make it so somebody like me can understand.
A. We do every day all the data, so I'm accustomed. What we're trying to do, the question is that is this average uncoated and the coated, are they significantly different, and this is a tool to determine that, and these values higher than the threshold value means significantly different. That's what in plain English that I can describe.
Q. Now, what is your opinion as to the statistical significance of what is reported in Dr. Gitis' tests?
A. That 95 percent confidence they're different.
Q. And is it a significant difference?
A. Yes.
Q. Okay. Now, could you turn to Exhibit 1378, please.
A. Yes.
Q. Now, did you hear Dr. Gitis talking about this chart yesterday?
A. Yes.
Q. Okay. Now, I don't want to go through it in great detail with you because he did, but what is this showing

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about the differences between pliability, knot run-down, friction, chatter, and tissue drag?
A. He's showing in a very simple way that based on the averages how much percent difference between the uncoated and coated, and the coated has a base line, then you get 64 percent higher value getting more stiffness, and the first one is pliability; the next, knot run-down, 81 percent; friction, 77 percent; chatter, 55 percent higher; tissue drag, he got static and dynamic was 30 percent static and dynamic, 56 percent. Please note they're all positive numbers, however, for the knot slippage beginning there is a decrease of 55 percent as well as a knot slippage untie 45 for the coated suture.
Q. We'll get to those just in a second. Let me talk about the other ones before we get to knot slippage which ones showing an improvement. Do these categories relate to the handleability and pliability issues we've been discussing?
A. Yes.
Q. And what does it show as to whether, what material effect coating has on those characteristics?
A. That a coating significantly improves each of these, these properties.
Q. Is this part of your -- did you rely on this in your opinion as to the material effect on coating on the basic and novel properties?

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A. Absolutely.
Q. Okay. Now, let me turn to the last two which are the knot slippage ones. What is your understanding of what characteristic the suture that's actually referring to?
A. This is related to knot security because if the knot slips, which you may expect the coating will do, and that's what it shows here beginning and then untie.
Q. Now, just so the jury understands, is that showing that the coating has a positive or a negative effect on knot security?
A. Coating has a negative effect on knot security.
Q. Okay. Now, did you have an opportunity to review the '446 patent, I assume you did?
A. Yes, many times.
Q. Right.
MR. SABER: Could you put that up on the board, Derek, as Exhibit 130.
Q. Now, my question to you, Dr. Mukherjee, does the '446 patent deal with knot security as one of the improved handleability or pliability aspects or as a physical characteristic of the suture?
A. Physical characteristic of the suture.
Q. Could you look at column 2, Derek, lines about -- why don't you start about line 63 or thereabouts down near the bottom. Could you read that, Dr. Mukherjee?

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A. "For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional heterogeneous fiber braid without sacrificing physical strength or knot security." The word that is important, "without sacrificing."
Q. Do you find that the coating actually does sacrifice the knot security?
A. Yes, sir.
Q. Thank you. Now, I think you made reference earlier in your testimony to Dr. Burk?
A. Yes.
Q. And did you review his report in rendering your opinions?
A. Yes.
Q. Okay. And what is -- could you describe generally what Dr. Burk did?
A. He was given two samples, one is A, the other is B, and he was told to tie knots relative to the two, and he came out with always A is better than the B.
Q. Okay.
A. Then it was identified A is the coated, B is the uncoated.
Q. Did you hear Dr. Gitis explain that the A was the coated and the B was the uncoated yesterday?

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A. Yes.
Q. Okay. Does it matter in your opinion whether the differences were just generally smoother, or is that enough in your opinion?
A. Oh, yes.
Q. Could you explain why?
A. Because, you know, it's a small difference like that is very big when they do the surgery because they don't want anything multipliers, if you have seen arthroscopy surgery, it's through little portals, and they have to do a lot of things. They don't want anything worse than the best.
Q. Okay. Now, let me ask you then based on all the evidence you've seen, what is your opinion as to why the coating on FiberWire materially affects the basic and novel properties of the '446 patent?
A. It does.
Q. Now, I want to ask you a few questions about Dr. Brookstein, if I could. Did anything that Dr. Brookstein testified about change your opinions?
A. No.
Q. Okay. I want to specifically ask you about some of the things that Dr. Brookstein testified about. Do you recall his testimony about the heat stretching?
A. Yes.
Q. Okay. Now, you had an opportunity to review his

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report?
A. Yes.
Q. Okay. And in his original report, did he make any reference to there being heat stretching of the FiberWire?
A. He may have. I don't remember.
Q. Okay. Do you have an opinion as to whether FiberWire is heat stretched?
A. Absolutely not.
Q. Okay. Can you explain why?
A. In order to stretch.
MS. ELDERKIN: Objection, your Honor. Objection. This goes to the manufacturing that we talked about this morning.
MR. SABER: I didn't ask him about that, your Honor.
THE COURT: Well, I'll hear where this goes. I'm not sure.
Q. Okay, go ahead.
A. May I answer that?
THE COURT: What's the question? Why don't you ask the question again.
Q. Let me try to rephrase to try and deal with this. Are you familiar with heat stretching processes?
A. Very much. I use myself heat stretching.
Q. Can you explain what heat stretching is?

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A. Heat stretching is when you make a fiber, you orient to make it stronger, and you apply, it's like a roller, you have one roller where the fiber comes in, the other roller you pick it up, and usually the roller on the pick it up runs much faster, sometimes four or five times faster than where the feed comes in. As a result, it's stretched. That's where it builds up strength.
Q. Now, you have experience doing heat stretching?
A. Absolutely.
Q. On braided sutures?
A. We did some braid, but I did a lot of monofilament sutures.
Q. Let's talk about the braided ones.
A. Okay.
Q. Does the heat stretching eliminate the need to put coating on braided sutures?
A. No.
MS. ELDERKIN: Objection.
THE COURT: Overruled.
Q. Could you explain why?
A. Because as I mentioned to you, there are two different operations. The stretching is to get the strength. Coating is to make it smooth. Now, when you make a braid, you end up with this rough surface, no matter what you do, it's universal so you got to have a coating.

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Q. Now, does the heat stretching process help or hurt pliability?
A. The heat stretching hurts the pliability.
Q. Could you explain, give an example to explain why?
A. Best example I can give you, if I may, if you got a guitar string and you pull it all the way, it becomes very stiff, so that's what the stretching does to the stiffness.
Q. Does the heat stretching fill in those bumps on the braided suture, those rough surfaces?
A. There's no way.
Q. Now, in the report that you reviewed from Dr. Brookstein, did you make reference to his scanning electron microscope?
A. Yes.
Q. Did you review what he had to say about that?
A. Yes.
Q. Okay. Now, are you familiar with that equipment?
A. Very much so.
Q. And in your experience, is scanning electron microscopes used to look at sutures?
A. Yes.
Q. And have you -- is that something you've done?
A. We have done several of those.
Q. Okay. Could you explain why scanning electron

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microscopes are used for sutures?
A. We -- as a lot of times the process of making suture used before that, we looked at the scanning electron microscopy and we see some damages. That kind of examination always goes on.
Q. And did you ever look with the use of a scanning electron microscope to look at the coating on sutures?
A. No.
Q. Could you explain why?
A. Coating, especially like a silicone coating is so transparent, it's colorless, so you cannot see anything.
Q. Now, did you ever have any discussions with your colleagues when you were at Davis & Geck as to what looking at a scanning microscope would show with respect to the coating?
A. Oh, yeah, because we were --
MS. ELDERKIN: Objection.
THE COURT: Overruled.
Q. Go ahead.
A. We were putting coating on Dexon sutures so we wanted to see at SEM nobody agreed, one person will say that there is, another person will say no, there isn't, so they were not really a very good test to find coating.
Q. If Dr. Brookstein had wanted to do a fair test with his microscope or something else, could he have done that?

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A. The only way is to put pigment into a silicone, you may.
Q. And did he do that as far as you know?
A. No.
Q. Now, in your opinion, sir, would a person with experience using a scanning electron microscope for suture ever use such microscope for the purpose of seeing coating on a suture?
A. No.
Q. Now, there was also some, you know, in Dr. Brookstein's report that you reviewed for your report, did he opine that the coating did not permeate into the braid?
A. Yeah.
Q. Okay. Into the FiberWire braid?
A. Right.
Q. Okay. In your opinion, sir, does it matter to affecting the basic and novel characteristics of the '446 patent whether the coating permeates the braid?
A. It does not.
Q. And could you explain why?
A. Yeah. Silicone is a coating, and its properties are more or less, more than 100 times lower than the polyethylene, so the sum of the mixture is better in the direction making it more pliable so it does not matter where the coating is going to go.
Q. And how about for handleability, does it matter where

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the coating goes?
A. No, it doesn't.
Q. Okay. Now, do you have an opinion as to whether in fact the coating on the FiberWire does get into the braid?
A. You know, it appears to me that it probably did.
Q. Okay. Why do you say that?
A. Again, this is I'm looking at the scanning microscope pictures. They appear to be there is something there. Now, I do not hang my hat on this observation. This is just kind of a, to some extent, stipulation.
Q. Now, are you familiar with I think you told me earlier that you're familiar with the coating process for braided sutures?
A. Absolutely.
Q. Is there anything in the braiding process that's used for braided sutures, coating process that's used in braided sutures that would allow you to come to the conclusion that the coating gets into the braid?
A. There is only thing because it's twice coated, there's a good chance it will get in and also the waking action, if you remember these little lamps that you put in the lamps and the oil goes up, that's the wicking effect so it may get in there from the operation itself.
Q. Could you explain a bit more about the wicking effect and what that has to do with coating processes for braided

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sutures?
A. Like I gave you an example, you take the wick in the lamp, then there's oil in the globe, and the way the oil gets in through the scapular through what is called the wicking action, and the same thing will happen when designing solution is going into the braid.
Q. Okay. Now, in your experience with the coating process that you're familiar with, is the oven part of that coating process?
A. The oven is used only for curing because there is a cross-linking, now, again, confusing term probably.
Q. Could you take a moment and explain what cross-linking and curing is?
A. What it is, if I can show you is like a fisherman's net, no nets are made, they're not connected. When you put the connection between the two linear separate threads, that's cross-linking, and silicone, if you cross-link, silicone is going to wash away so there's a small amount of benzoyl peroxide. That's the chemical to produce that effect so that's why you need the oven to cure it, nothing else.
Q. Can you coat silicone coating without putting it through the oven?
A. No.
Q. Okay. The -- I want to ask you some about what Dr. Brookstein said about Mr. Grafton's testimony to support

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his opinion. Do you agree that Mr. Grafton's opinion supports Dr. Brookstein's?
A. No.
Q. Could you explain why?
A. Mr. Grafton was talking about putting the PE to that polyester so he can tie knots. Other than that, he didn't say anything else.
Q. Was he talking about the knot security when you say tieing knots? I'm not sure what you're talking about.
A. He was talking about the ability to tie knots.
Q. Now, is the coating added for reasons different than what Mr. Grafton was talking about?
A. Yes.
Q. Could you explain what that is?
A. The coating, as I was explaining, is the ease of tieing knots and the suture passing to the tissue, so those are very different needs than just ability to tie knots.
Q. Okay. Now, the -- I want to talk to you a little bit about what the patent teaches, the '446 patent teaches as far as adding coating, if I could, sir. Why don't you put up Exhibit 130, please. Okay. This is the '446 patent. Does the '446 patent disclose that there are problems with using coating?
MS. ELDERKIN: Objection.
THE COURT: Sustained.

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Q. Let's -- could you turn to column 2 of the '446 patent, lines 11 to 13. 11 to 13.
A. Yeah.
MR. SABER: Derek, can you get that up.
Q. 11 to 13. Could you get that highlighted.
A. I can read from here.
Q. Why don't you read that sentence?
A. "The enhanced pliability of a braided -- "
Q. The line 11, this is column 2.
A. Oh, column 2, I'm sorry.
Q. I want to make sure we're in the same place.
A. I'm sorry. "Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures."
Q. Could you explain what this sentence is teaching to someone ordinary skilled in the art?
A. What they're showing, the difference, meaning the coating so they have to have better solution than the coating.
Q. Let's move down to lines 55 to 58 of column 2. Could you read that sentence, please.
A. Yeah. "The dissimilar," from there on?
Q. The highlighted sentence.
A. Okay. "Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical

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interlocking or weaving of the individual yarn."
Q. What is your understanding that's being taught in this sentence?
A. This is all about the patent that is teaching the mechanical interlocking is a way to improve the properties. You don't need coating.
Q. Okay. And let me ask you about one other part of this patent, if I could. Could you turn to column 6, starting with line 13 down to about the end of that paragraph.
A. "However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening."
Q. Okay. What is your understanding what's being taught by this sentence, sir?
A. This is for a person with the ordinary skill would learn that you do not need coating, you have the yarns doing the job, the lubricious yarns.
Q. Now, in your opinion, sir, does FiberWire use the teachings of the '446 patent as it applies to the need to use coating?
A. No.
Q. And could you explain why?
A. All over like the '446 patent, the whole patent is about

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these two kinds of yarn, one is lubricious strength and the interlocking of the two, and they discourage use of coating.
Q. Does FiberWire use coating to meet its handleability needs in your opinion?
A. Yes.
Q. And in your opinion, what does that say about whether FiberWire is using the teachings of the '446 patent as it applies to coating?
A. FiberWire is teaching to use the coating.
Q. Okay. Let me ask you just one last question, Dr. Mukherjee. In your opinion based upon everything that you've looked at, does FiberWire infringe the claims of the '446 patent?
A. No, absolutely not.
Q. Okay. And just in a sentence why is that?
A. Because the FiberWire patent says --
Q. The '446 patent? Are you talking about the '446 patent?
A. I'm sorry, I'm getting mixed up, the '446 patent discloses the use of lubricious yarn and the yarn with the strength interlocking and does not say anything about coating.
Q. All right. And is it your opinion, sir, that the coating -- what is your opinion as to whether the coating on

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FiberWire materially affects the basic and novel properties of the '446 patent?
A. It does improve the handling and the pliability.
Q. And -- go ahead.
A. And at the same time, it appears that the physical properties such as knot security goes down.
Q. Okay. And are those material effects on those basic and novel properties in your opinion?
A. Yes.
MR. SABER: I have no further questions, your Honor.

CROSS-EXAMINATION

BY MS. ELDERKIN:
Q. Good morning, Dr. Mukherjee.
A. Good morning.
Q. You and I haven't had a chance to talk before?
A. Yes.
Q. My colleague, Mr. Bonella, took your deposition a little over a year ago?
A. Yes.
Q. Now, before he took your deposition, you put in several reports that set forth your opinions in this case, correct?
A. Yes.
Q. And your reports set forth not just your opinions but

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your bases for those opinions, your reasons for those opinions; is that right?
A. Say that again.
Q. And in your reports you set forth not just your opinions but your reasons for your opinions?
A. Yes.
Q. And then at the deposition, Mr. Bonella had the chance to ask you about your opinions and what you relied on in forming your opinions, right?
A. Yes.
Q. Now, you agree that the main issue in this case is whether the coating on FiberWire has a material effect on the basic and novel properties of the patent invention, right?
A. Yes.
Q. It's not whether the coating on FiberWire has any effect, correct?
A. It depends on how you are defining. I would say any effect.
Q. So it doesn't have to be a material effect?
A. Yeah, material means important.
Q. Right?
A. That's what you're saying.
Q. And to determine whether that effect is important, you have to know what surgeons think, correct?

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A. Yes.
Q. In fact, I think you said in your direct testimony it's very important to know what surgeons think about the sutures when you're developing them?
A. Yes.
Q. So, you relied on Dr. Burk's, didn't you, Dr. Burk put in an expert report?
A. Absolutely.
Q. And I think you showed it as Exhibit 1309. It's about a three-page double spaced typewritten report, right?
A. It could be.
Q. And you talked about the test that he did, that he compared sutures and he was able to tell the difference between what he was told was coated and what he was told was uncoated, right?
A. Afterwards the test.
Q. Exactly, exactly. But you only relied on Dr. Burk's reported in forming your opinion, didn't you?
MR. SABER: Objection. Objection, your Honor. That's inconsistent testimony.
Q. With respect to Dr. Burk, you only relied on his report, you didn't talk to Dr. Burk?
A. Is that what you're asking?
Q. You didn't talk to Dr. Burk?
A. I didn't talk to Dr. Burk, no.

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Q. Before forming your opinion, you didn't read his deposition or watch the tape of his deposition, did you?
MR. SABER: Objection, your Honor.
THE COURT: You know, let me just see you at sidebar.
(THE FOLLOWING OCCURRED AT SIDEBAR:)
MS. ELDERKIN: This goes directly to the credibility.
THE COURT: That's fine. I'll redirect on this other issue, and what you heard, you're opening up the door to what I barred. Excuse me, Ms. Elderkin.
MR. SABER: I don't mind if she asks him about his deposition, but to say that term that he didn't look at his deposition when his report was before the deposition.
MS. ELDERKIN: This is at his deposition he was asked.
MR. SABER: I thought you asked about his report.
THE COURT: You're opening it up.
(SIDEBAR CONFERENCE WAS CONCLUDED)
Q. Now, Dr. Mukherjee --
THE COURT: I'm just wondering based on my ruling did you want to reask the question?
MS. ELDERKIN: No.
THE COURT: All right.
Q. Well, I will ask the question, you did not talk to

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Dr. Burk before you rendered your opinion, did you?
A. That's correct.
Q. Now, in the beginning of your testimony, you talked about a Maxon suture?
A. Yeah.
Q. That you said you developed?
A. Yes.
Q. And there's a patent on the Maxon suture; is that right?
A. Yes.
Q. But you're not listed as an inventor on that patent; is that correct?
A. That's correct.
Q. And you were very proud of that invention, right?
A. Yes.
Q. You worked hard on it?
A. Absolutely.
Q. And you didn't -- did Davis & Geck give that to its competitors to use for free?
A. Not that I know of.
Q. They wouldn't do that, would they? Now, you talked about another suture, a polypropylene suture?
A. Yes.
Q. FiberWire is not a polypropylene suture, is it?
A. No, but polypropylene is one of the constituents in the

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lubricious yarn that in No. 1 is polypropylene.
Q. Right. You talked about a Dexon braided suture, about the coating on a Dexon braided suture?
A. Yes.
Q. That's not FiberWire either, is it?
A. There's only one FiberWire.
Q. Right, right. I'm just trying to correlate what you talked about for the jury. The Dexon suture and whether it needed a coating or not, I wanted to make sure the jury understands that's a different suture than FiberWire.
A. But the problem is the same, whether it's Dexon or FiberWire, if you have a rough surface, surgeons cannot use it.
Q. I'd like to ask you about some of the other things that you did or did not consider before you formed your opinions. Now, when you talked in your direct testimony about silicone coating, which is the coating on FiberWire, right?
A. Correct.
Q. But when Mr. Bonella took your deposition last year, you didn't remember what FiberWire's coating was, did you?
A. It might have slipped my mind at that time.
Q. Would you like to see your testimony on that? Your deposition on page 458.
A. Which one, this book?
Q. The one that has -- that might be exhibits.

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A. This is the one?
Q. Right. Look at page 458.
A. 458.
Q. You can look at lines 8 to 11. I'm sorry, I'm transposing numbers here, page 485.
A. 485?
Q. Yes, I apologize.
A. No problem. That happens to me all the time.
Q. Hopefully not as much as me.
A. I'm sure it does more for me.
MR. SABER: Can I join that club, too?
Q. Page 485, lines 8 to 11, did Mr. Bonella ask you, "Do you know -- do you know what the coating is on the FiberWire?" Did you answer: "I don't remember. I cannot guess right now"?
A. Yes, I see.
MR. SABER: Your Honor, may I read the next two lines, please?
MS. ELDERKIN: I'll read the next two lines: "Did you ever ask what the coat was in --" Answer: "Oh, yeah, but I don't remember."
Q. Now, Pearsalls makes the braided material that's in the FiberWire suture, correct?
A. Yes.
Q. And before you formed your opinions in this matter you

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had never been to Pearsalls, had you?
A. No.
Q. And you were here in the courtroom when Dr. Brookstein testified last week, I think?
A. Yes, I was here.
Q. You heard him say that he went over to England and he inspected the manufacturing facilities for Pearsalls?
A. Yes, but I saw a videotape of the manufacturing process of Pearsalls.
Q. Oh, you did?
A. Yes.
Q. Well, you didn't see that videotape before you formed your opinions, did you?
A. No, because I saw it very recently.
Q. Right, right. That was after the fact, but when you formed your opinions in this case, you had never seen the manufacturing process at FiberWire?
A. But I'm familiar with the coating process, ma'am. It's really nothing new for me. Coating is a coating, a silicone coating of a suture.
Q. Right. But you've heard the testimony in this case, there was a lot of discussion about the manufacturing process?
A. Yes, there is.
Q. Before you rendered your opinion, before you arrived at

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answer, I do not know."
A. The word does not mean anything, a monofilament or multifilament.
Q. You did not ask for any clarification of the question?
A. That's my mistake. I should have.
Q. And did you didn't know of the suture bending strength or stiffness strength is a function of the number of the fibers in the suture, did you?
A. In a braid, once the braid is constructed --
Q. Dr. Mukherjee.
A. I said I do not know the answer if you are asking that.
Q. You did not know in your deposition?
A. Yeah.
Q. And when you were asked at your deposition, you didn't know whether the fiber and fiber mobility affects the multifilament suture's bending strength; is that correct?
A. That's what I said.
Q. That's what you said. You talked about a knot slippage strength test that Dr. Gitis carried out?
A. Yes. Where are you?
Q. I'm not on a page yet.
A. Oh, okay.
Q. When you had your deposition taken, you were not familiar with how the knot slippage test that you relied on

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was carried out, were you?
A. In fact, I looked at his report. If you look at reference 3, it is our work in our lab. Schubert is an Ob.Gyn resident working in my lab, and that's the procedure he followed.
Q. That's the procedure he followed?
A. Yes.
Q. Let's see what you say in your deposition, if we could. Could you look at page 450, please, line 6 to 9. Do you see that you were asked, "And the test before that, the knot slippage test -- "
A. Yes.
Q. "-- are you familiar with how those tests were done?" And you answered, "No." That was your testimony at your deposition, wasn't it?
A. I misspoke because I knew exactly what that test was.
Q. Now, is it your testimony that the coating on FiberWire makes the knot slippage strength of FiberWire worse but it detracts from the knot slippage strength of FiberWire?
A. Say that again.
Q. Do I understand your testimony that you gave here today to be that the coating on FiberWire actually detracts from the knot slippage strength of the FiberWire braid?
A. What is the word "detracts"?
Q. Lessens?

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A. Yes.
Q. Sacrifices?
A. Okay.
Q. Did I understand your testimony to be that the coating sacrifices the knot slippage?
A. That's what the data said.
Q. That's your opinion?
A. That's what the data showed.
Q. Right. It's your opinion that that's what happened?
A. That's what the data, yes.
Q. Right. Does FiberWire have inadequate knot security?
A. You know, I have not done -- you're asking something I have not done. I don't think there is a problem there, but it is uncoated and coated comparison test that you're talking about.
Q. Right.
A. That doesn't mean it does not have knot security.
Q. Do you think that Arthrex sells a suture that has inadequate knot security?
A. Absolutely not.
Q. And when you were analyzing Dr. Gitis' data like the knot security data, you didn't do any analyses of the data to see how it compared to sutures in general to see if any of the effects were material, did you?
A. I have enough knowledge in the suture industry that I do

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not have to go in and look for every one of them because, as I said, I live with the sutures. I mean, if you've been in my lab, there's a lot of projects going on right now.
Q. Could we look at your deposition, sir, page 454, lines 3 to 7. You were asked, were you not, "Did you do any analysis of any of the CETR data to see how it compares to sutures in general to determine whether -- any effects on the material?" Answer: "No, I did not." That's what you said at your deposition, correct?
A. That's what I said.
THE COURT: How much longer do you have?
MS. ELDERKIN: We should take a break, but it's probably about 15 minutes or so.
THE COURT: I don't want to wait. Why don't we just take our break now.
THE CLERK: All rise for the jury.
THE COURT: I want to see counsel about scheduling off the record.
(Discussion held off the record)

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A. Synonymous, yes.
Q. The same thing. In fact, the heading on your slides, those animation slides that you used, said both "knot run-down" and "knot tie-down" in the caption, right?
A. Okay.
Q. And it was your testimony that the coating on FiberWire actually improved the knot tie-down of the FiberWire; isn't that correct?
A. Yes.
Q. Okay. Let's look at the Hunter '446 patent for a minute, if we can. That's Plaintiff's Exhibit 130. I'd like to look at Column 6, Lines 5 to 8. And you see that, and do you see how it says there that "If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tie-down performance of the braid"?
A. Yes.
Q. So the patent expressly teaches that you can put a coating on the braid to get better knot tie-down performance, just like the coating on FiberWire? Isn't that the case?
A. Not really.
Q. Let's look at the friction test that you considered. Now, again, you didn't provide any input to Dr. Gitis on how he performed these friction tests, did you?
A. No.

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Q. And you're not familiar with how he performed the friction tests, are you?
A. Not specific tests, no.
Q. Right. So you don't know, for example, if he maintained constant pressure on the sutures when they were being tested, do you, constant tension on the samples?
A. Is it pressure or tension? What are you talking about?
Q. I'm sorry. You don't know if he maintained constant tension on --
A. Tension on what?
Q. Tension on the sutures?
A. As he was pulling through? Oh, coefficient test, okay, all right.
Q. Coefficient test, right. So you don't know if he maintained constant tension on the sutures when he carried out the friction tests for all these different samples, do you?
A. Well, ma'am, this is very -- he's very well known. His lab is well known.
Q. You don't have any personal knowledge of that, though, do you?
A. Not that specific. He has a reputation, so I believed in him and his expertise.
Q. And when you were asked at your deposition, you didn't have or remember any friction data for other sutures to put

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the Gitis friction results into context, did you?
A. See, I probably at that time did not remember. I'm pretty conversant with the friction data, yes.
Q. At your deposition -- let's look at Page 453, Lines 17 to 22 -- is it the case that you were asked, "Have you seen any data to put other data of other sutures of what their coefficient of frictions were?" And your answer was, "I don't remember. I've seen my own eyes working suture but not -- I don't remember."
So at your deposition you didn't remember seeing friction data for any other sutures so that you could put the data for FiberWire into context with what the results are for other sutures; isn't that correct?
A. That's what I said, ma'am, but I know what they are.
Q. Right. Well, at your deposition you didn't tell us, did you? And in fact you didn't do any analysis of any -- well, scratch that. And then you're aware, aren't you, that after Dr. Gitis did his report that you relied upon, he determined that there was a physical data corruption in his friction data?
A. That's what I came to know afterwards, yes.
Q. Right, and that's the data that has been presented here in court, isn't it?
A. Yes.
Q. And the chatter data that Dr. Gitis relied on, that's

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actually taken from that same friction data, isn't it?
A. Yes.
Q. The chatter results, the same friction data that has physical corruption, correct? The chatter is a measurement of how rough the surface of the braid is; is that right?
A. Yes.
Q. You told us at your deposition, didn't you, that you didn't have an opinion about how the coating affects the chatter of FiberWire suture; isn't that right?
A. I don't remember.
Q. Okay, well, let's look at Page 456, please, Lines 10 to 14. You were asked, "So you started by saying 'no' to my question. So do you have any opinions about how the coating affects the chatter of the suture, of the FiberWire suture? Answer: The answer is 'no.'" Was that the question, and is that your answer?
A. I misspoke, yes.
MR. SABER: Your Honor, may I read in?
THE COURT: Yes.
MR. SABER: Starting on Line 7, "And Norm, again, is a person to explain more about the individual data points as well as the averages."
Q. And you're not aware of typical chatter values for other sutures, are you, so that we can make some kind of comparison between the chatter data that Dr. Gitis presented and you

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A. Correct.
Q. And hot stretching can make the surface properties of a nonabsorbable suture a little softer, can't it?
A. No.
Q. No? Well, let's look at your deposition at Page 107, please, 107, Lines 9 to 13. Do you see where you were asked, "What does hot stretching do to the surface properties of nonabsorbable sutures?" And your answer, "It makes it a little softer so that the fiber-against-fiber friction is reduced." That was the question and that was your answer, right?
A. Right.
Q. And hot stretching can affect the handling properties of the suture, can't it?
A. Let's see, what are you reading?
Q. If you'd like to see your testimony, it's at Page 108, Line 25, to 109-2. The question was, "So hot stretching operations you say can affect the handling properties?" And you answered "Yes." That was your testimony, right?
A. Yes.
Q. And hot stretching can also affect knot strength properties, if you look down at the next lines; isn't that the case?
A. Yes.
Q. Now, you considered the Hunter '446 patent in arriving

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at your opinions? That's right?
A. Yes.
Q. Okay. And I think you referred to a portion of the patent this morning in your testimony in Column 2. I'd like to bring that up again. It's Column 2, Lines 55 to 58, if we can bring that up on the screen, please. And in particular I think you focused on the sentence that starts "Instead." You said, "Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns." Do you remember talking about that this morning?
A. I did.
Q. And I think you said that it was due to the materials and not the coating, the properties of the braid, right?
A. Please read entirely.
Q. Entirely.
A. So it tells very, very definitely that the mechanical interlocking is going to do the job, so you don't need a coating.
Q. Right.
A. That's how I interpreted that.
Q. Okay. But this sentence isn't talking about a suture. It's talking about a braid, isn't it?
A. Sutures are made from braid.
Q. Well, but this sentence is saying that the integrity of

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the braid and the properties of the braid is due to the mechanical interlocking or weaving of the individual yarns, isn't it? It's not talking about the suture?
A. Well, braids and sutures, they're all used -- I can see right now in your patent, I'm sure that they're used interchangeably.
Q. Well, let's look elsewhere in the patent. Let's look at Column 6, if you would, and that paragraph from Lines 5 to 17. And let's focus on that first sentence there starting at Line 5 that says, "If desired, the surface of the heterogeneous multifilament can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tie-down performance of the braid."
Isn't it correct that that's what the Hunter '446 patent says?
A. It says -- just, please, you know, you are reading, so let me just say what I understood from this. "If desired." It doesn't say it requires, so "if desired." Yeah, I can go to Detroit or I can go to New York, whatever you want to do, but it does not say that it is required to put a coating, so it's not -- it's not really emphasizing the need for coating in this sentence.
Q. It's saying you can do it, or you don't have to do it, right?
A. Right, so it's, like, do it or you don't do it.

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Q. In fact that's what you said at your deposition, isn't it? You said, "You can if you want to"?
A. Sure. But when I'm reading the sentence here in the patent, that it's saying that "if desired," so it doesn't say you should.
Q. Right, "if desired." Let's look at what you said in your deposition at Page 345, Lines 1 to 6.
A. 335?
Q. Yes, 345, Lines 1 through 6.
A. 345.
Q. And so Mr. Bonella was referring you to this paragraph in the patent, and he asked you, "Aren't the inventors saying they envisioned their invention to be -- you could either coat the suture or not coat the suture?" And your answer was, "Yeah, they are not -- definitely with any of these, you can if you want to." That was your testimony, wasn't it?
A. Yes.
MS. ELDERKIN: Thank you, Dr. Mukherjee.
REDIRECT EXAMINATION BY MR. SABER:
Q. How are you doing, Dr. Mukherjee?
A. I'm doing so far all right.
Q. Okay, we'll have you out of here in a few minutes.
A. Great, thank you.
Q. I just want to follow up on what -- it's high-tech stuff. It's a little too much for me. The paragraph that

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Ms. Elderkin was just asking you about in the patent, in the '446 patent, does the paragraph go on to --
A. Yes.
Q. Well, let me ask you my question.
(Laughter.)
Q. Does it go on, as you read the patent, to say that it's best not to use coating?
A. That's what it's saying if you read the entire part. "However," I think that's what it says there, "if the surface of the --" I can't read it. Yes. And -- well, no, not there.
Q. Okay, yes, what does that sentence say?
A. Which one?
Q. It's highlighted now.
A. Oh. "However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated, saving expense as well as avoiding the associated braid stiffening."
Q. What's your understanding of that sentence?
A. That definitely discourages a person of ordinary skill to use coating. It says: Don't use coating. It's expensive. It stiffens the braid. Therefore it's no good.
Q. Okay, thank you. Now, Ms. Elderkin asked you a lot of questions coming out of Mr. Bonella's deposition of you where

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she was asking whether you said you had no opinions on certain FiberWire factors. Now, do you recall at your deposition, was Mr. Bonella asking you over and over again about individual data points in Mr. Gitis' report?
A. Yes.
Q. And what was your view toward asking questions about individual data points in Dr. Gitis' report?
A. Well, with respect to his opinion, I mean, Mr. Bonella's opinion, he's not familiar with looking at the data. So that's where he's taking one point compared to the other point. Instead, what is normally done is a statistical average.
Q. Now, when you answered the questions that Ms. Elderkin asked you about where you didn't have an opinion, were you talking about just comparing individual data points?
A. That's what data all the time is going on, so that's what I was -- my mind was trying to react to that.
Q. Right. Did you tell Mr. Bonella that your opinions were based on the statistical analysis of the averages?
A. I told him many times in my deposition.
Q. And did you have opinions about the effect of FiberWire based on the statistical analysis in Dr. Gitis' report?
A. Absolutely.
Q. And did you tell Mr. Bonella that time and time again during your deposition?

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A. I did.
Q. Okay. Let's talk just about one or two of those, if we could, just so the record is clear on this point. Could you turn to Page 464 of your deposition. Could you read for the record starting on Line 5 through Line 20.
A. "Question: Dr. Mukherjee, for any of the data that was reported in Dr. Gitis' report, do you know why there was any variation between samples and the data? Answer: Specifics I cannot tell you, but I have done enough testing in my life. It does happen. Question: Did you? Answer: There are many, many explanations, and Norm Gitis will be able to tell you that. Again, I draw your attention to the table that I base my opinion on, expert opinion based on Page 16, and that's where -- that's how normally done. As an expert in analyzing data, I have done plenty and I am still doing this, that statistically there is significant difference from the coated or uncoated, and that is my report."
Q. Did you tell Mr. Bonella over and over again that there was a statistical difference between coated and uncoated FiberWire based upon your analysis of the statistical data?
MS. ELDERKIN: Objection.
THE COURT: Sustained.
Q. Are you an expert on analyzing statistical data?
MS. ELDERKIN: Objection.
A. Yes.

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THE COURT: Overruled.
Q. And did you tell that to Mr. Bonella during your deposition?
A. I probably said that I used statistics but I'm not an expert. Again, that's what I answered.
Q. Okay, I want to talk about one other entry on Page 235. I think I'm going to start on 234. Perhaps I'll read it to you here starting on Line 15: "C for Sample No. 2 of the coated, Dr. Gitis determined the stiffness was 7.53 times 10 to the minus 7? Answer: Yes, I do see. Question: And for Sample 6 of the uncoated --"
A. Wait a minute. Which page again?
Q. On Page 434.
A. 434.
Q. Yes. Oh, I'm sorry if I said the wrong --
A. I'm sorry. Yes.
Q. Okay, and starting on line 15, Mr. Bonella asked you: "C for Sample No. 2 of the coated, Dr. Gitis determined the stiffness was 7.53 times 10 to the minus 7?" And you answered, "Yes, I do see." Then he asked you, "And for Sample 6 of the uncoated, he determined the stiffness was 8 times 10 to the minus 7? Do you see that?" And you answered "Yes." Then he asked you, "Are those two numbers statistically different?" And then after some objections, you answered, "In addition to that, there are one number you

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can't compare. That's why the statistical analysis was done on the average and the standard deviation. That's the only way that I know that you can make a judgment between the two groups of data."

Were you explaining to Mr. Bonella why it's inappropriate to just use the analysis based on individual data points?

MS. ELDERKIN: Objection.

THE COURT: Well, I'll ask, what were you doing there, since that's leading?

MR. SABER: Okay.

Q. What were you doing in that?

A. Okay, Mr. Bonella was speaking of the usual data points, and I kept telling that you have to use the averages and use a statistical analysis to make any meaning whether they're different or not different.

Q. Okay, let me move on to another topic. Ms. Elderkin asked you a series of questions about whether you knew about the specific setups of Dr. Gitis' tests. Do you recall that?

A. Yes.

Q. Okay. And who was responsible for the specific setups?

A. Dr. Gitis.

Q. Did you rely upon what Dr. Gitis did on the specific setups?

MS. ELDERKIN: Objection.

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THE COURT: Overruled.

A. Yes, I depended on him.

Q. Okay. Is that appropriate for an expert in your position to do?

MS. ELDERKIN: Objection.

THE COURT: Overruled.

A. Yes.

Q. Okay. Did you have a general understanding of the kinds of tests that he did?

A. Yes.

Q. Okay. Now, Ms. Elderkin asked you a question about Mr. Gitis' pliability test, and you were in the middle of an answer when she kind of stopped you from talking about whether his test was appropriate. I'd like you to be able to finish your answer, if you recall what you wanted to tell the jury about Dr. Gitis' pliability test.

A. What he did is determined the lasting modulars by doing a tensile stress strength, we call it. In other words, you pull it and you measure the load and the different -- I mean the displacement. And he calculated from that -- that is the modulars. That's like a fingerprint of the material, how stiff that is. And then you put into the equation E times I. I is the letter of geometry. Since both the sutures, the diameters are so close, really the geometry does not play a very important role. It's only the E. And the value of E

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was lower for the coated, higher for the uncoated.

Q. Was Dr. Gitis' test, in your opinion, an appropriate test to use?

A. Yes.

Q. Okay. Now, one last topic I want to cover. You know she asked you about Ms. Willobee's tests?

A. Yes.

Q. Or Ms. Holloway's tests when she did it?

A. Yes.

Q. Can you look at Exhibit 1026. I think you'll find it in the book that I gave to you earlier.

A. Yes.

Q. Have you got it?

A. Yes.

Q. Okay. In the description of the test, did Ms. Holloway describe that it's a test between coated and uncoated FiberWire?

A. Yes.

MR. SABER: Okay, I have no further questions.

MS. ELDERKIN: Just two, your Honor.

RECROSS-EXAMINATION BY MS. ELDERKIN:

Q. Mr. Ficocello, could you pull up the patent again, Column 6. If we can pull up the patent again, the Hunter '446 patent, Column 6, Lines 13 to 17, that sentence that starts with the word "however," Mr. Saber asked you about

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that, and I believe you said that that was a teaching that the patent discourages coatings, correct?

A. That's what I said, yes.

Q. Right. And it says that you can eliminate them because by eliminating the coatings, you can avoid the associated braid stiffening, right?

A. Yes.

Q. Now, Dr. Gitis' tests showed that the coating on FiberWire makes the braid less stiff?

A. Correct. That's the way it happens.

Q. Right. The coating on FiberWire isn't making them stiffer, right?

A. That's what we found.

Q. That's right.

MS. ELDERKIN: Thank you.

THE COURT: Thank you very much, sir.

THE WITNESS: Thanks.

(Witness excused.)

MR. SABER: Your Honor, now we're going to just read in a few very short deposition designations. Do you want to read, or do you want to answer?

MR. TAMBURO: Do you mind if I get in the witness stand?

THE COURT: You know, some lawyers --

(Laughter.)

EXHIBIT 11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS
	)	Pages 143-290
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY TWO
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 7, 2007 9:02 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

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person of ordinary skill in the art.
THE COURT: Just make sure it's phrased consistent with what you both asked for, but, more importantly, you agree that's the standard. I think you do, right?
MR. SABER: Oh, yes, that's the law.
THE COURT: That's the law, okay, all right.
(End of side-bar conference.)
MR. BONELLA: Your Honor, I have that information. The stipulated fact is, "A person of ordinary skill in the art is a person having undergraduate --"
THE COURT: Now, just slowly so they can understand it. So the standard here is, what does somebody of ordinary skill in the art understand? So they've agreed on who that person is. That's a stipulation, which means that you can accept it. So why don't you slowly so they can understand.
MR. BONELLA: Sure. "A person of ordinary skill in the art is a person having an undergraduate degree in engineering or science and several years, approximately three to five years experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications."
Q. Dr. Brookstein, let me ask you, are you a person of ordinary skill in the art?
A. Yes, I am.
Q. Do you have at least an undergraduate degree in

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engineering or science?
A. Yes, I do.
Q. And do you have several years, at least three to five years experience with the manufacturing and/or processing of fibers and sutures?
A. Yes, I do.
Q. And is that experience with fibers and sutures that can be used for biomedical applications?
A. Yes, that is.
Q. When you're doing your analysis to determine what is a material effect, are you determining it from a person of ordinary skill in the art?
A. I didn't -- could you repeat that?
Q. Sure. When you're doing your analysis to determine whether FiberWire's coating has a material effect on the novel and basic characteristics, are you doing it from a perspective of a person of ordinary skill in the art?
A. Yes, I am.
Q. Thank you. So we're going to talk a little bit about pliability, and I'd like to go to Plaintiff's Exhibit 629, if I could. I'd like to explain what pliability is, Dr. Brookstein, so we can help understand the novel and basic characteristics.
Okay, this graphic, did you prepare this?
A. Yes, I did.

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Q. And this is a demonstrative exhibit?
A. Yes, it is.
Q. Okay, what are we looking at here?
A. We're looking at something that would be what we call a monofilament, a single homogeneous cross-section of a fiber.
Q. Okay, can you just briefly and generally, what is pliability?
A. Pliability is a way to discuss or describe how much something can bend, how much load it takes to bend something.
Q. And can you contrast that with maybe pulling on something?
A. Yes. We can take a structure, a linear structure like this monofilament suture, and we can pull on it, and that would be putting some tension, and we'd be measuring the tensile properties. Or we can bend it, and we're measuring what we call the bending properties or the pliability properties.
Q. Okay. And what we have here you said diagrammatically is a monofilament suture?
A. This one is a monofilament, that's correct.
Q. Now, a monofilament suture, its pliability is a function of what parameters?
A. It's a function of its diameter.
Q. And what do you mean by diameter?
A. The D, the distance from one end of one -- I'll just do

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this. That's the diameter, okay?
Q. Okay, what else is a monofilament suture pliability the function of?
A. It's also a function of what we call the suture modulus. Modulus is a way to describe how much resistance there is when you pull on something, okay? So the higher the modulus, the stiffer it is when you pull on something.
Q. Now, you just said pulling, and we're talking about bending.
A. That's correct.
Q. And you use those two concepts?
A. Yes, because what happens is, when you bend something, in fact on the outside of the bend you're stretching it, and on the inside of the bend you're compressing it. So that's why we use the tensile properties to help you determine what the bending properties are.
Q. Is that always true, or is that just true for monofilaments?
A. That's only true for monofilaments. It's only true for monofilaments.
Q. Okay. Now, the next element you have there is the suture cross-sectional geometry. Can you explain what that means and how that relates to pliability.
A. Yes. I show here a circular geometry, but as you might imagine, you can have geometries that are not circular, that

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 683-904
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY SIX

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 14, 2007 9:03 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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spoke to the, you know, the law firm to get that idea, then I looked at the literature from the Ethicon Depuy Mitek papers and several other authored documents, Depuy documents. I could list all of them.
Q. I'm not asking you to. I'm just trying to get a general idea of the things you did. Did you review any test results?
A. Yes. I actually got involved in the testing and planning phase with Dr. Gitis, and I reviewed his results, and then I was told about some surgeon relation, but I decided not to get into that, and that's why on the deposition I didn't ask for Dr. Burk's deposition.
Q. Okay. Did you review his test report that he had done prior to his deposition?
A. Yes, I did.
Q. Okay. Is that referenced in your report?
A. Yes.
Q. Okay. And did you use your years of experience that you described to the jury in rendering your opinions?
A. Absolutely. I'm more than 30 years of experience. I live with sutures, I smell sutures, that's what I do.
Q. Dr. Burk, who actually uses the suture products, who's the ultimate end user?
A. It's the surgeons.
Q. Now, is it important as the suture manufacturer to

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understand the needs of surgeons?
A. Absolutely. We always, even for the early part of the development phase, when we were making polymers, we always speak to surgeons.
Q. And why do you do that?
A. Because they're the customer. Like you develop something, whether it's a toy or a fabric or whatever, you look at who is using it and what the requirements are, and you try to satisfy those on met needs.
Q. Now, did you come to an opinion as to whether the coating on FiberWire affects the basic and novel characteristics of the '446 patent?
A. The coating -- what is your question again?
Q. Did you come to an opinion as to whether the coating on FiberWire affects the basic and novel characteristics that you see in the claim construction?
A. Yes, I did.
Q. What is your opinion?
A. That it does affect the basic and novel characteristics.
Q. Is that a material effect in your opinion?
A. It's a material effect.
Q. Now, when you rendered your opinions on this matter, did you render it from the position of one of ordinary skill in the art?

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A. Absolutely.
Q. Could you explain what is the ordinary skill in the art here?
A. My experience, I hire a lot of people in the suture industry. They should have a science and engineering degree, about two to three years experience working in the suture company.
Q. Now, you see in the claim construction there's a term called "handleability" and term "pliability." Could you explain what that means?
A. Yes, sir.
Q. Sure.
A. Pliability is -- I'll give you a very simple example. If you take a small steel rod and you bend it, it's very stiff, but if you take a straw that you drink your soda, you bend it very easy, and that's pliability.
Q. How about handleability?
A. Handleability is a mixture of many things, but the first thing is the feel. And the suture, you give it to a surgeon's hands, how is the tactile feeling, then comes how does he tie the knot, what happens when the one strand goes with the other and then whether the knot is secure or not. All these things go in to handleability.
Q. Okay. How about as the suture is being used going through tissue, is that part of handleability?

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A. Absolutely, absolutely.
Q. Okay. Now, I know we've had a lot of terms thrown around in this case, and I don't want to take long. I think the jury's start to get at, so perhaps if I could ask you a few of the terms you made, if you could just explain them to the jury. I think you talked about, just mentioned that a suture running down -- the knot running down the suture. What is that called, and can you explain that to the jury?
A. Knot run-down, this is one term used that when you -- especially when you do the arthroscopic knot, you tie the knot at the top, and the knot has to slide all the way down. That's the knot run-down.
Q. Okay. And how about the word, "chatter." You've heard that in this case. Could you explain what that is?
A. Yes. Chatter is whenever there is friction that it produces a lot of resistance, there's a measure of how rough the surface is.
Q. And I think suture slide, is that the same thing as the knot? What is suture slide?
A. Well, suture slide is a lot of different things because when you take one up strand and it goes with the other, it's a very important property. In fact, I learned, if I may say so, maybe I take a little bit of time, when I was developing polyethylene suture, the suture was breaking, and our straight pull and knot pull is much higher than our

EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff

-VS-

ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants

CA No. 04-12457-PBS
Pages 430 - 522

JURY TRIAL - DAY FOUR

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 10, 2007, 9:00 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

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A. Yes, I had to go look that up. I thought it was $100,000 a year, which was what I had testified at in the deposition, but it's actually $50,000 a year.
Q. Does Arthrex also compensate you for your expenses when you lay out travel expenses and the like?
A. Yes. They reimburse me, yes.
Q. And the rest of the money that you've received for the work you've done for Arthrex has been through royalties; is that correct?
A. Correct.
Q. Do you have a sense over the ten plus years that you've been working with Arthrex about how much you've received in royalties?
A. Well, yes, but let me say, I'll preface that by saying that it is a merit-based system, and it's a percentage; and if you have products that are good, that are popular, that sell a lot, you make more money, but -- so you want a dollar figure, you mean, basically?
Q. Yes, as best as you can describe it.
A. It's somewhere over $8 million.
Q. And that's over about what period of time?
A. Over -- well, since 1995, so about twelve years.
Q. Now, let me turn a little bit to FiberWire, what we're here talking about today. Did you have any involvement with Arthrex in working with FiberWire?

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A. I was involved as maybe the main or one of the main consultants with FiberWire. I'm not on the patent. I'm not an inventor of FiberWire.
Q. Okay. Could you tell, though, does that fall into some of the consulting kind of work that you told the jury about, what you did with FiberWire?
A. Yes.
Q. Could you explain generally what it is that you did with FiberWire. We'll get into some specifics in just a minute, but if you can generally tell the jury the kinds of things that you've done with FiberWire.
A. Well, the way it began with FiberWire was the way it worked with a lot of the patents and a lot of products that Arthrex had. Don Grafton, in addition to being someone I worked closely with, became a good friend, and he would come to San Antonio because a lot of their testing we did in those days was actually in Texas at Rice University. And so he would bring things, products that were being developed at the time, and show them to me, and so he had mentioned some ideas about this.
The way I actually first saw the first sample, I guess, or the first iteration of the FiberWire, or the FiberWire precursor, I was actually at Naples, Florida, Arthrex's headquarters, to do some other work, and I was there with another doctor, Dr. Casey Chan. And it just so

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happened that the first samples of this FiberWire precursor had come in, and so Don asked us to have a look at it, see what we thought about its characteristics, its handling characteristics, and even its strength, because Dr. Chan had brought with him a special tester that he had designed for testing knot security, so we tested it and tried it and tied it.
Q. Well, do you know what you called this early precursor? I mean, is that a prototype? Is that the word that --
A. That was a prototype, yes.
Q. Okay. But this early prototype or precursor, do you know whether that example had coating on it, whether it was coated or not?
A. No, the original one that we tested that day did not have coating on it.
Q. Okay. Now, did you do an evaluation of how that prototype handled?
A. Yes. We tested the knot security with Dr. Chan's testing machine, and we felt the knot security wasn't particularly good. And also I felt that the handling characteristics weren't good in this one.
Q. Okay, what did you do to test the handling characteristics?
A. Well, I tied knots. I just -- you know, you get a feel for how the thing ties. You do it both with your bare hands

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and with gloves on. And my feeling was, it had too much friction, too much drag, and I was having a lot of trouble tying knots with it that were secure.
Q. Okay. Did you talk to Mr. Grafton about your observations on the handleability aspects?
A. Yes.
Q. And what did you tell him?
A. Well, I told him that, you know, I liked his idea of a high-strength suture, obviously, but he was going to have to basically get some better handling characteristics, have it so it had better run-down basically when you try to push the knot down, and that he was going to have to, as you would expect on any braided suture, have a coating to it.
Q. Did you have a discussion with Mr. Grafton about the need to have a coating on FiberWire?
A. Yes.
Q. Okay. Now, those discussions that you had with Mr. Grafton about the need for coating, was that for however FiberWire was going to end up?
A. Oh, absolutely. I mean, every braided suture worth its salt has a coating on it, so --
Q. And could you explain what you mean when you say that, that every braided suture worth its salt has to have a coating on it?
A. Well, the thing about braided suture is it's basically

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bumpy, and it has a lot of friction. It has, you know, a high coefficient of friction relative to other types of suture; for example, the monofilament, which is just a single strand and doesn't have a lot of friction to it. So you have to have some way to smooth out the bumps, and a coating is a very tried and true tested type of way to do that.
Q. Now, I think you mentioned sliding through suture. Could you explain to the jury what that is? Sliding the suture and sliding through suture, you used a couple terms there.
MS. ELDERKIN: Objection. Expert.
THE COURT: Overruled.
Q. Go ahead, you can answer.
A. Well, the suture has to slide actually through a number of different interfaces. It has to slide against each other, so, you know, when you tie a knot, you have two suture strands. So if you have one braided suture strand against another suture strand, if they have a very high friction and a lot of bumps, you're not going to be able to slide them as well.
They also have to slide through soft tissue, so you're pulling your suture through, for example, tendon; and if it's too bumpy, it actually tends to cut the tendon. In fact, there are some mechanical saws that are based on that principle of having bumps on them. They actually can even

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saw through bone.
And, in addition, it has to pass through various things like cannulas. It has to pass through a plastic cannula. It has to pass through the eyelets of the anchor as you pull through. It has to pass through the openings in the suture pass-throughs that it draws in the suture passer. So you hit friction every step of the way.
Q. Dr. Burkhart, I know that may be a little bit complicated for the jury. Could I ask you to just step down and perhaps draw on the easel some examples of what you may be speaking about. I'm just going to move this over here. We'll try and get it so the Judge can see and the jury can see, and the lawyers too.
A. Okay. Well, I'm not really an artist, not even close, but I'll do my best here.
THE COURT: Do you know what I think? Even though it might be an issue for me, if you got a little closer to the jury. I think I'll move down. I don't know that people can necessarily see it.
(Witness at easel in front of jury.)
A. So let's use an example of a torn rotator cuff. This would be the humerus, which is the bone. Basically you've got bone here. And then you've got your rotator cuff which is torn loose from the bone, which would be -- you've got muscle out in this area but then tendon here, which is that

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gristly fibrous tissue. And you've got to reattach this down to the bone where it's pulled away from. It's actually torn away from the bone.
So the way you do that is, you have a suture anchor, which is something, for example, a biodegradable screw that has an eyelet to it here with sutures attached to it. You have to remember the skin is out here too. It's kind of like building a ship in a bottle. So you've got to start at a distance, and then you have to -- you have to start outside where you can handle things, deliver them inside at a distance. So you have to have ways to do that, and you're working through cannulas, little tubes that your instruments can go through.
Okay, so basically you're going to have sutures here, so we'll draw one limb of the suture that's out here. This limb you're going to have to pass through the tendon, and you're going to have a small instrument that either pulls it through or that pushes it through. So let's say that we have what we call a retrograde pass-through that comes through, and it has a jaw to it, and it has something like this, a little hook so that it grabs it and pulls it through. So there's going to be friction created between the jaws of the instrument and the sutures so it pulls it through.
Then you're going to grab this with another passer

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and pull this suture limb out here through the cannula. So it has friction coming through the cannula because there has to be a little rubber diaphragm here to prevent the fluid from all escaping.
So then what you do is, you tie a knot. You'll bring your two suture limbs together, and you'll have a very complex sliding knot, but you'll have a lot of surface area between the sutures and the weave back and around, but still be able to push the knot down. But you can't have so much friction that the knot stops halfway down, or then you've lost your fixation, you don't have any fixation. So you have friction at this point.
You have a knot pusher as well. Typically it's a little tubular thing with a hole in it -- we call it a cannulation -- that pushes your knot down and helps you with that. And then once this base knot is down, then you have to throw some more half hitches, which are some additional throws that come down on the top.
So the frictional points that you have really, they're going to have friction at your eyelet here. You're going to have friction coming through the jaws of your instruments. Every time you pass it, you can have friction through the soft tissue, which if it's too rough, potentially your suture will just cut through the soft tissue and destroy a part of your soft tissue, which is the worst possible

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scenario. You have friction here between the suture and your instrument, and then you have major friction here between the two limbs of your sutures. So that pretty much sums it up, I think.
Q. Okay, just to help the jury a little bit, Dr. Burkhart, could you just mark on your drawing the places where the friction occurs and just what they are.
MS. ELDERKIN: Objection. Expert testimony.
THE COURT: Overruled.
Q. Go ahead, you can do that, sir.
A. Okay, so friction occurs here where the red is at the eyelet. It occurs here where the suture is passing through the instrument.
Q. And could you just write down some words for the jury.
A. Oh, okay, sure. Okay, so friction. So at the eyelet of the anchor, and it would occur at the jaws of the instrument. It would occur at the soft tissue. It would occur at the cannula, which is this tube that it passes through. And it would occur at the knot where it's suture against suture. And it would also occur at the knot pusher, at the interface between the knot pusher and the knot.
As I get lower, I'm getting more and more like a doctor's handwriting there too. Okay.
Q. And could you just mark, I guess, in red, just to complete the drawing, the friction points, just so that we

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know where they are.
A. Okay, here, here, here. There would also have to be an instrument this side coming in. That would be another suture retriever to grab that suture, so it would be another one with a jaw like that. So that would be another friction point. And there, there, both ends of the cannula, and then the suture against suture and then knot pusher against suture.
Q. Thank you.
MR. SABER: Your Honor, I'd like to mark Dr. Burkhart's drawing as Exhibit 1377.
THE COURT: As an exhibit?
MR. SABER: Yes. This is what he created in court.
MS. ELDERKIN: Objection.
THE COURT: Sustained.
MR. SABER: Thank you. Let me move this back and --
THE COURT: You know, witnesses are allowed to teach you, and both sides have done that by drawing you pictures. In the olden days, we actually called them "chalks." When I started as a judge, they were literally done on a chalkboard, but now we have all this high-tech stuff. So this is to help you to understand, but it's not an exhibit in the sense that an accurate picture is, and that's sort of that little debate we were just having. So you can

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use it to help understand the issues, but it is not an exhibit. It's obviously not an exact replication of tissue and the like.
(Witness resumes the stand.)
Q. Now, one of the things I think you told the jury a bit about was as the suture was going through tissue. Have you heard the term "tissue drag"?
A. Yes.
Q. Does that relate to what you were telling about the suture going through tissue?
A. Right. It just relates to the friction of the suture as it comes through the tissue.
Q. Okay. And can you explain to the jury what would happen if you had poor tissue drag?
A. If you have excessive drag with more friction, then you worry about it actually cutting the soft tissue, and that's something that surgeons are faced with quite often. Particularly, if you can imagine someone has a rotator cuff tear anyway, they're going to have rather poor tissue relative to someone who's healthy; and then if you're going to challenge it even further by having suture with a lot of drag and you potentially tear that tissue in half, then you may end up with a situation where you just can't repair it.
Q. Now, when you discussed the need for coating with Mr. Grafton, what relationship did that have to these

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friction points that you testified about?
A. Well, it had everything to do with it because as a surgeon in the operating room, you've got to have -- you can't tolerate a high-friction suture. You just can't tolerate it. You have to have enough friction to hold the knot. You have to have enough pliability that it turns back on itself, but you have to have something that slides and doesn't damage tissue.
Q. Now, these issues that you spoke about, are they important to you as an orthopedic surgeon?
A. Absolutely.
Q. And could you explain to the jury a bit why they're important to you.
A. Well, you know, speed is important for a lot of reasons. Obviously, you want a surgeon who's meticulous, but you want a surgeon who can do it on a timely basis as well because speed is important. In fact, if you look at things like infection, the one factor that has always been related to infection has been length of operation, and the longer the operation, the higher the chance of infection. So that's just one thing that's drilled into you as you're going through your surgical training. But speed is important. If you can reduce the length of the operation, you reduce the chance of infection, you reduce the chance of complications from anesthesia. It all adds up.

EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff

-VS-

ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants

CA No. 04-12457-PBS
Pages 430 - 522

JURY TRIAL - DAY FOUR

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 10, 2007, 9:00 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

Page 479

Q. Now, does Arthrex advertise that FiberWire has revolutionized orthopedic surgery?
A. We've advertised it, but essentially our customers told us that that's what it would do.
MS. MALINOSKI: Objection.
THE COURT: Sustained.
Q. You've advertised it?
A. Yes.
Q. Okay. Could you put up Exhibit 62, please. There we go. Could you tell what Exhibit 62 is, Mr. Benavitz.
A. Yes, a brochure.
Q. And a brochure for what?
A. For FiberWire primarily.
Q. And is this a brochure that you use to help market products?
A. Yes, it is.
Q. And is this where Arthrex states about revolutionizing orthopedic surgery?
A. Yes, it is.
Q. And what was your involvement in making that assertion?
A. I was the product manager at the time, and so a lot of the copy, I had suggested some of the copy along with input from others, but that's how that piece came about.
Q. And does it being a high-strength suture, does that permit new things to be done? Or how does that work?

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MS. MALINOSKI: Objection.
MR. SABER: Let me rephrase that, your Honor.
Q. Why do you believe it revolutionizes orthopedic surgery?
A. Well, again, essentially that's what our customers had told us time and time again.
THE COURT: You know what, that's hearsay, so --
THE WITNESS: I'm sorry.
Q. What can it do that's revolutionary and different?
MS. MALINOSKI: Objection.
THE COURT: Overruled.
A. Well, it allows a surgeon to tie knots arthroscopically without breaking the suture, and it allows him to get through the case and perform a successful case, and that's helped them do that.
Q. Does it permit procedures to be done better?
MS. MALINOSKI: Objection, your Honor. He's actually leading the witness with the exhibit rather than the witness testifying.
THE COURT: You've been leading him, so why don't you just ask him.
MR. SABER: Okay.
Q. Could you tell the jury some examples of how FiberWire has helped revolutionize orthopedic surgery?
MS. MALINOSKI: Objection. Lack of foundation.
THE COURT: Overruled.

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A. Well, one interesting example here locally is that during the playoffs for the '04 --
THE COURT: No, no, no, no, although they may want to hear the answer, but, no.
Q. Okay. Well, could you give some other examples then of how it's helped revolutionize --
THE COURT: Just we're talking about the properties, handleability, pliability. You need to tie it into this case.
Q. Okay, let me move on then to the handleability. Does Arthrex promote the handleability aspects that you've talked about for FiberWire?
A. Yes, we do. In fact, in that brochure, it clearly talks specifically about the handleability and the characteristics of the suture when the surgeon is using it, which is a very important part.
Q. Could you blow that part up there so the jury can see it. Could you read what this paragraph says.
A. Yes. "Tie ability and knot profile" is the subject. "Orthopedic surgeons enthusiastically endorse FiberWire for its feel and knot tie ability. The first throw stays down facilitating reproducible tissue repair. Sliding knots advance smoothly, easing arthroscopic knot tying procedures. Superior strength allows tighter loop security during knot tying, increasing knot integrity while reducing the knot

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profile compared to standard polyester suture."
Q. But is there anything added to FiberWire that Arthrex asserts is used to meet these needs?
A. Yes. There is a silicone coating that's standard on the suture.
Q. Okay, let me ask you a little bit about some of those things. Could you put up Exhibit 1106, please. Mr. Benavitz, could you identify what Exhibit 1106 is, please.
A. Yes. This is "Important Product Information." It comes packaged with every suture that we have, every FiberWire suture.
Q. Why does Arthrex use the term "important product information"?
A. Because it's important. It's key that the surgeon know what's contained in this particular information brochure that's packaged with the product.
Q. Does this information brochure, including the Important Product Information, make any assertions as to what the coating on FiberWire does?
A. Absolutely.
MS. MALINOSKI: Objection. Leading.
THE COURT: Overruled.
A. Yes. It talks about the key components in the construct of the suture, including the silicone coating.

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Q. Okay, could you read for the jury specifically what it says.
A. The highlighted part?
Q. Yes, please.
A. "The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing through tissue."
Q. Now, could you take a look at Exhibit 1350, please, and, Mr. Benavitz, could you explain what Exhibit 1350 is, please.
A. Yes. This is again another promotional piece, a brochure, if you will, for FiberWire.
MR. SABER: And, your Honor, I move to admit Exhibit 1350.
MS. MALINOSKI: No objection, your Honor
(Defendant Exhibit 1350 received in evidence.)
Q. And in Exhibit 1350, does Arthrex make any statements about what the coating does?
A. Absolutely, yes.
Q. Could you explain to the jury what that is.
A. The statement basically says, "Coating provides smoother tying characteristics."
Q. And why does Arthrex make that statement to the public?
A. It's a key part of the suture's design. It's what makes it be able to be used by surgeons.

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Q. Now, has Arthrex ever considered selling FiberWire without a coating?
A. No, absolutely not.
Q. And why is that?
A. All braided suture, to my knowledge, or 99 percent of it is coated. It's standard practice. It's a known. Surgeons expect that, and they expect it because it helps in, again, the tie ability and the handling of the suture. It's an important part of that.
Q. Do you believe that you'd be able to sell FiberWire if it didn't have a coating?
A. Not very well, no, if at all.
MR. SABER: I have no further questions, your Honor.
CROSS-EXAMINATION BY MS. MALINOSKI:
Q. Good morning, Mr. Benavitz.
A. Good morning.
Q. All set?
A. Oh, yes.
Q. Okay, Mr. Benavitz, on your direct exam, you did a lot of talking about FiberWire and the construction of FiberWire. Do you remember that?
A. Yes.
Q. And do you remember I took your deposition a few days ago, and you told me that you never had any training on

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making sutures, right?
A. That's correct.
Q. And you have an engineering background, right?
A. That's correct.
Q. And that you're not an expert in the particular materials or biomaterials that are used in sutures, right?
A. Well, I guess it depends on what you mean by "expert." I'm well aware of the materials. I've been involved with them for the entire time that they've been developed relative to the FiberWire products. I've been involved with testing of the product and at-length discussions with engineer groups and surgeons about the material, and I'm familiar with the mechanical properties of the material.
Q. Okay, well, that's interesting because when I took your deposition a few days ago, you actually said to me, "I'm really not an expert on, you know, materials, biomaterials, and mechanical testing." Do you remember that?
A. I remember your question, but I'm not sure exactly what you were getting at with some of the questions.
Q. Okay. And you also told me that you had no engineering input into what the structure of FiberWire was, didn't you?
A. Well, yes, the engineer actually designed it with the manufacturer. The manufacturer was essentially the expert in the manufacture of the sort of materials, so I didn't have input on how to design the fibers or how to braid them.

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That's a process done by the outside manufacturer.
Q. Okay, that's not really what my question was. My question was, did you have any role in deciding what particular materials would be used in FiberWire?
A. No, I did not.
Q. And it's only the Arthrex engineers who were the ones involved in developing FiberWire, right?
A. Well, there was feedback from the marketing people's standpoint, which is my position, which is, we had to make sure we let them know what our surgeons wanted in terms of what were they looking for? And we then let the engineers and the manufacturing people, who are the experts from that side, say, "Well, these fibers are strong. This is the braid configuration that you need that's standard and the coating." And that sort of things were decided by the engineering and manufacturing. And it's very classical for the marketing people to say, "This is what our customers want," and then we let them decide that.
Q. Mr. Benavitz, that really wasn't what my question was. Let's go back to something else you just said. You said that you actually interact with the surgeons because they're your customers, and you want to get their feedback, right?
A. Yes. Yes, ma'am.
Q. Okay. And isn't it the case that Dr. Burkhart was really the primary or the key surgeon on the FiberWire

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Q. Okay, now, that's one of Arthrex's brochures that it used in actually selling FiberWire, right?
A. Yes, ma'am.
Q. Okay. On the first page it refers to it as being a polyblended suture, right?
A. Yes, ma'am.
Q. It doesn't refer to anything about the coating on FiberWire, right?
A. Not on the front page, no, ma'am.
Q. Okay. Okay, let's take a look at it. If I look at the page ARM 10565, are you there?
A. Yes.
Q. Okay. Now, I don't see any references to coating anywhere in this brochure.
A. Well, the reference is in the middle part, and we've gone over this. It's the tie ability knot profile.
Q. Okay, let's look at these. Let's start at the top. It focuses on, first, the braided jacket, right? It says, "Fiberwire's suture is constructed of a long chain polyethylene core with a polyester braided jacket that gives FiberWire superior strength, feel and abrasion resistance," right?
A. Yes.
Q. It doesn't mention the coating, right?
A. Not there, no, ma'am.

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Q. Okay. And then we go down to strength. It talks about, "FiberWire has greater strength than comparable size standard polyester sutures," right?
A. Yes.
Q. Again, it's just talking about the construction of FiberWire, not the coating, right?
(Witness examining document.)
A. Yes.
Q. Okay. And then let's take a look at the section that says "tie ability and knot profile." You got it?
A. Yes.
Q. Okay. Now, when it talks about tie ability and knot profile, it talks about, "Orthopedic surgeons enthusiastically endorse FiberWire for its feel and knot tie ability," right?
A. That's what it says, ma'am.
Q. Okay. And then it talks about, "Its superior strength allows tighter loop security during knot tying," right?
A. Yes. Those are all things that are needed to have a suture perform well, and the coating lets that happen. And it's a known fact that coating --
THE COURT: You know what, answer her question, okay?
THE WITNESS: Okay.
MS. MALINOSKI: Thank you, your Honor.

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Q. Okay, and then we have "abrasion resistance." Do you see that next?
A. Yes, ma'am.
Q. Okay. And when it talks about abrasion resistance, what the brochure talks about is, "The ultrahigh molecular weight polyethylene core dramatically increases FiberWire's abrasion resistance," right?
A. Yes.
Q. Okay. And then on the Page ARM 10566 -- are you there?
A. Yes.
Q. Okay. On the top it talks about FiberWire, and it talks about it being a new generation of polyester suture with long chain polyethylene core, right?
A. Yes.
Q. And it talks about it having greater strength as similar size polyester sutures, right?
A. Yes.
Q. It talks about the superior feel, right?
A. Yes.
Q. And lower knot profile, right?
A. Yes.
Q. And the only thing that is discussed in that paragraph is the FiberWire construction of the braid itself, right?
A. Yes.
Q. So we talked about the jacket, right? The braid of the

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polyester and polyethylene, right. We talked about the polyethylene core, right? And those are the only things that are called out in terms of FiberWire in this brochure, right?
A. In this brochure, yes.
Q. Correct, in this brochure. Okay, we can look at another one if you want. We'll look at DePuy Mitek Exhibit 20. Do you have that in your book too? It should be in that little black book you have up there.
A. Yes.
Q. Got it? Okay. Now, again let's look at FiberWire. It's an orthopedic composite suture, right?
A. Yes.
Q. Okay. And that's referring to the construction of FiberWire as a composite of polyethylene and polyester, right?
A. Yes.
Q. Okay. Then under exceptional strength, it talks about the blend of ultrahigh molecular weight polyethylene multifilament core, doesn't it?
A. Yes.
Q. And then it refers to the braided polyester and polyethylene jacket, right?
A. Yes.
Q. No coating, right?
A. Not mentioned in this brochure.

EXHIBIT 14

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS
	)	Pages 143-290
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY TWO
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 7, 2007 9:02 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

THE COURT: That's in evidence already. It's in.
MS. ELDERKIN: This is a different, the original assignment of the assignment to Ethicon.
THE COURT: I see.
(Assignment to Ethicon was marked Plaintiff's Exhibit No. 562 and admitted into evidence.)
A. Do you want me to explain that?
Q. Yes, please. Could you describe briefly what this document is?
A. Yes, so within Johnson & Johnson, Ethicon would make an invention, there's an assignment process, and this is the form that you signed to assign the invention to the employer.
Q. So you assigned the rights to your employer?
A. Yes, as part of my employment agreement.
Q. Thank you. If you go to page 2 of the document, that is your signature, Mark Steckel?
A. Yes, sir.
Q. That's the date, February 17th, 1992?
A. I assume so, yes.
Q. Thank you. Now, Dr. Steckel earlier you talked about reasons why you were not able to commercialize the invention. Do you recall that discussion?
A. Yes.
Q. I think you said it was not commercially feasible at the

time. Do you recall that?
A. Correct.
Q. Isn't it true you were having serious manufacturing problems with these braids and that's why you didn't commercialize them?
THE COURT: I think we should move on as we discussed.
MR. TAMBURO: Let me just have half a second here. No further questions, thank you.
THE COURT: Anything?
MS. ELDERKIN: No, your Honor.
THE COURT: Thank you very much. You can leave.
MS. ELDERKIN: Your Honor, we thought we'd like to play the tape of Mr. Grafton.
THE COURT: Do we have any other live witness right here?
MS. ELDERKIN: We do, although this is sort of a predicate to his testimony.
THE COURT: Okay. Then we'll be showing you the tape of Mr. Grafton that we sort of aborted late yesterday. He was the vice-president of engineering at Arthrex.
(Videotape was played as follows:)
Q. Good morning, Mr. Grafton.
A. Good morning.
Q. Can you please state your residence.

A. 4218 Skyway Drive, Naples, Florida, 34112.
Q. Thank you.
- - - -
Q. And when did you start at Arthrex?
A. I think it was 1991.
- - - -
Q. When did you first get involved with sutures?
A. When we started manufacturing suture anchors for shoulder arthroscopy.
Q. When was that?
A. I don't recall the date.
Q. And what was it -- do you remember -- called the first suture that Arthrex sold?
A. Yes. It was a company in New Mexico that manufactured the material. It was a polyester material.
Q. Was that a Tevdek suture?
A. No.
- - - -
Q. Okay. What suture was that?
A. I don't recall the name of it.
Q. You don't recall the name?
A. No. It was a secondary company.
- - - -
Q. Did it have a core?
A. I -- we didn't design it. We purchased it as an OEM, so

I can't tell you that.
- - - -
Q. Okay. Eventually, was this suture replaced?
A. Yes.
Q. Okay. What was it replaced with?
A. With a Pearsalls suture -- polyester suture.
Q. 100 percent polyester suture?
A. To my understanding, that's correct.
Q. Was that a braided suture?
A. Yes.
- - - -
Q. Was there any problem with this polyester suture from Pearsalls?
A. It was stiff. And the -- that was the main complaint; although when I say complaint, it was not a widely-spread complaint. But the suture was not as compliant as the sutures that were on competitive anchors.
- - - -
Q. When you say not as compliant, what do you mean by that?
A. Surgical feel, tactile feel of the suture by the surgeon.
Q. Did the 100 percent polyester suture from Pearsalls have a coating on it?
A. Yes.

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Q. What was the coating?
A. I have no idea.
- - - -
Q. Was this a suture that Pearsalls had designed for Arthrex, this 100 percent polyester suture, or was this one that was already being made?
A. I don't remember.
Q. You don't remember? Sorry, I misspoke earlier. I said Mr. Lawson. And I should have said Mr. Lyon. It's Lawson Lyon.
A. Yes.
- - - -
Q. The 100 percent polyester suture from Pearsalls, did it have a core?
A. Don't know.
Q. Don't know? And the polyester that was braided in the polyester suture from Pearsalls, do you know what type of polyester that was?
A. No.
Q. When's the first time that you went over to England to visit Pearsalls?
A. Don't remember.
- - - -
Q. What was the next suture that you can remember Arthrex selling?

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A. Jenzyme Tevdek.
- - - -
Q. Okay. Did you recommend that Arthrex sell the Tevdek sutures?
A. From an engineering standpoint, the material met the specification or engineering requirements to be used with a suture anchor.
Q. And what were the engineering requirements that you reviewed Tevdek suture for?
A. Knot strength, tensile strength, color, biocombatibility. You know. It's -- on and on.
Q. Knot tiedown? Is that one of the considerations?
A. Knot -- knot strength.
Q. Was knot tiedown one of the considerations that --
A. Well, obviously if you are going to tie a knot, I mean, it's going to be tied down to something. Yes. The makeup of the suture anchor, so, yes.
- - - -
Q. The Tevdek suture, was that also polyester?
A. Yes.
- - - -
Q. After -- let me back up. Any problems with the Tevdek suture?
A. Yes.
Q. What were the problems with Tevdek suture?

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A. Tensile strength was low.
Q. Any others?
A. That's enough.
Q. Okay. Were there --
A. That kill the product.
Q. Okay.
A. Others were -- the others were insignificant, if there were some. That killed the product.
Q. That killed the product?
A. Yes.
Q. Okay. How about the knot strength of the Tevdek suture? Was that low?
A. If your tensile strength is low, sir, we're talking about straight pull, knot pull, that would cover both categories.
Q. Okay. So the knot strength of the Tevdek suture was low, too?
A. Yes.
Q. And so that was the part of the reason why the Tevdek suture was killed? Is that the word?
A. Yes.
Q. How about the knot tiedown Tevdek suture? How was that?
A. I have already been through that with you. We tested for tensile strength in knot and straight pull; okay? So to

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answer your question, if those were low, then -- you would expect the knot tiedown, the term you had been using, to also be low.
- - - -
Q. Is it -- were these complaints from surgeons about the Tevdek suture, about the strength?
A. That's correct.
Q. And is that when the development of FiberWire began?
A. Yes.
- - - -
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- would you like the story of how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it

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was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, document friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr. Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a Glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said he kind of jokingly. He said, "And I didn't even work out the day before."
And so he was trying to be nice about it, but bottom line was your sucks. Okay?
And so -- you know -- we're in a position where we need to find a such that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.

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I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?
A. That's correct -- make some size 2 braided material, send to me, and at the -- coincidentally, at the same time I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who as an R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up. We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.
So at that point in time, it looked like we would not be able to use an alternative material of ultra high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.
I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra high molecular weight polyethylene to enhance the or reduce the knot slipage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra high molecular weight polyethylene PE, of adding the PET and his -- I'll never forget the e-mail. He thought that was a

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killer idea.
And so I had asked then at that time for Brian Hallett to make me samples of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.
- - - -
Q. Okay. Dr. Chan?
A. Dr. Casey Chan, that's correct.
Q. And the testing that you conducted with Dr. Burkhart and Dr. Chan on the ultra high molecular weight polyethylene was a knot strength test?
A. Knot security.
Q. Knot security test?
A. Yes.
Q. Was that the test we see in Exhibit No. 421?
A. That's correct.
Q. And you said the strength was excellent I believe of the initial prototype but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the

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existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And the slippage was such that it was determined that a higher ultra high molecular weight polyethylene prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively)
Q. Ultra high molecular weight polyethylene, is that a lubricious material?
A. Yes.
Q. And was the knot slippage of this ultra high molecular weight polyethylene poor security because of the lubricity of the polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?

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A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra high molecular weight polyethylene was poor, the prototype, right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that it was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question. Did Dr. Burkhart say that your idea to braid PET with the ultra high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra high molecular weight

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polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra high molecular weight polyethylene had good knot security?
A. Yes.
Q. And the prototype of PET and ultra high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with ultra high molecular weight polyethylene, was it -- did it

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have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively.)
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?
Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. Was that part of your initial idea, or was that -- because I thought you said your idea was to add the PET. Was it also to coat it or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.

- - - -

A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probably that the suture came as -- the second prototype -- as coated.

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Q. That was standard for them to coat it, in other words?
A. Yes.

- - - -

Q. I show you Depuy Mitek Exhibit 324. Do you recognize Exhibit 324 as a letter from you to Mr. Hallett?
A. I don't recall the letter, but I recognize my name and the contact person. But the specific circumstances of the letter, I don't remember.

- - - -

Q. When you had the prototype of PET and ultra high molecular weight polyethylene made, do you know if Pearsalls specifically made that or if they just pulled it off their line from something?
A. I'm sure they made it.
Q. They specifically made it?
A. Yes.
Q. It's not like they had a product that they could just give to you?
A. No.

- - - -

Q. And then you say can you build a 25 percent Dyneema/75 percent polyester blend in size 2 that is very flexible (like the existing suture or the Ethicon sample) and send it to me to test; do you see that
A. Yes.

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Q. Does the Ethicon sample, does that refer to an Ethibond?
A. Yes.
Q. And you say, "If we get the -- " "If we get this blend correct, we will have a terrific advancement in suture for our soft tissue anchors." Do you see that?
A. Yes.
- - - -
Q. I would like to know what you mean by in your letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in size 2 that's very flexible. And then you said, "If we get this blend correct, we will have a terrific advancement."
What did you mean by, "If we can get this blend correct"?
A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively)
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?

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A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?
A. (Witness nods head affirmatively.)
Q. What about the knot security?
A. Yes.
Q. So you were varying the amount and type of the materials to get optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
A. Yes.
- - - -
Q. And before, I think you told me that you came up with the idea of braiding PET with ultra high molecular weight polyethylene?
A. Yes.
Q. And that was what Dr. Burkhart referred to as the killer idea, right?

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A. Yes.
- - - -
Q. Okay. Let me just say for the record Exhibit 423 is Bates numbers ARM 283 through 287. Is this a patent that you applied for that developed out of your work with the FiberWire?
A. Yes.
THE COURT: Can we hold it for a second. People can stand and stretch. I know sometimes it's hard to listen to this length.
MS. ELDERKIN: That's it, your Honor.
THE COURT: It's over?
MS. ELDERKIN: That was over.
THE COURT: Good. All right. Let me just ask, maybe there's some agreement here. Let me make sure the jury understands what is tensile strength.
MR. BONELLA: Dr. Brookstein the next witness is going to explain in detail. You take a suture you want to pull on it like this. It's the amount of strength it takes to pull on it relative to how much it stretches.
THE COURT: Do you agree?
MR. TAMBURO: We agree. It's a stretching strength.
THE COURT: All right. You know what, it turns out they disagree. Put that on hold and hopefully the

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experts which you'll hear will explain it. It's just a material that was used a lot.
MR. TAMBURO: Slight modification, tensile strength, when you take the suture and pull it apart, when it breaks. I think we're in agreement on that.
MR. BONELLA: Yes, but you also measure the force along the strain curve.
THE COURT: The hand motions for the record if you were took a thread, at what point it would break?
MR. TAMBURO: Break, yes.
THE COURT: Okay. Thank you. Who's our next witness?
MR. BONELLA: I'd like to call our next witness, Dr. David Brookstein, please.
DAVID STUART BROOKSTEIN, having been duly sworn by the Clerk, testified as follows:
THE CLERK: Would you please state your name and spell it for the record.
THE WITNESS: Yes. My name is David Stuart Brookstein, David, Stuart, S-t-u-a-r-t, Brookstein, B-r-o-o-k-s-t-e-i-n.
DIRECT EXAMINATION
BY MR. BONELLA:
Q. Good morning, Dr. Brookstein.
A. Good morning, Mr. Bonella.

EXHIBIT 15

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 523-682
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY FIVE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 13, 2007 9:04 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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(Resumed, 11:40 a.m.)
THE COURT: Bring in the jury.
Let me just say, have you had a chance to look at each other's jury instructions, both the little quick ones that came up this morning.
MR. TAMBURO: Briefly, yes.
THE COURT: I thought they both seemed roughly okay.
MR. TAMBURO: There's one issue with the --
THE COURT: All right, we'll talk about it later. Just it was my instinct during the break, so. . .
MR. TAMBURO: Yes, your Honor.
THE COURT: I was also going to add a stipulation, by the way? "There were some things that you should treat the defendants Arthrex and Pearsalls as the same, so you need not decide separately with respect to each of them," because they've heard a lot about both, and I wasn't positive they'd understand why.
MR. TAMBURO: That's fine, your Honor.
THE COURT: So tribology, when you have the American Indian tribes, is that the same route? So how does that relate to friction?
THE WITNESS: No, no, just a coincidence.
THE COURT: It has nothing to do with it. It must come from the Latin or something, right?

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THE WITNESS: For some time, I understood it this way. It's not your American Indian tribes.
THE CLERK: All rise for the jury.
(Jury enters the courtroom.)
MR. SABER: May I proceed?
THE COURT: Yes.
BY MR. SABER:
Q. Welcome back, Dr. Gitis.
A. Thank you.
Q. Before the break we were talking about your tests, and I want to move to the next one, the knot slippage test. Now, I know you testified earlier that you were asked to look at knot security. Does knot slippage test relate to knot security?
MR. BONELLA: Objection.
THE COURT: Overruled.
A. To the best of my understanding, knot slippage test gives very good characteristic of knot security or knot strength, or whatever other terms are used.
Q. Okay. Could you turn to Exhibit 1365.
A. Yes.
Q. Could you explain what Exhibit 1365 is, this demonstrative exhibit?
A. It shows the -- it illustrates the schematics of our knot slippage test. It's different from the previously

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described pliability test. In particular, now we have a knot on the suture, and also now we have a suture in form of a loop. If you remember in the tension pliability test, it was just a single suture. Now we've got a loop of the suture tied with a knot. And the lower end is wrapped around a stationary rod, and the upper end of the suture loop is wrapped around upper rod which is moving up vertically, exactly as it's shown here. And the sensor continuously monitors the vertical rod.
And to characterize knot slippage and knot security, we use two parameters; one parameter, the force at the very moment of the beginning onset of knot slippage; and the other parameter is the force at the knot failure. And typically in the literature, the knot failure is defined as either knot being untied or when slippage reaches and exceeds 3 millimeters.
Q. So do I understand you had to measure two different things; is that correct?
A. We monitored force, and we recorded two different values, two different levels of force, maximum force before slippage and then force at the moment of knot breaking.
Q. Now, what machine did you use to do this test?
A. We used the same UMT2 as we used for all other tests, and it's the same UMT2 which we sold to Ethicon, U.S. Surgical. We used our patented universal tester for all

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suture tests.
Q. Okay. Now, let's move to Exhibit 1372.
A. Yes.
Q. What is this, Dr. Gitis?
A. This shows the results of our knot slippage test. On the left you will see is a graphical representation, and on the right you see the summary table. If you look at the plot, force versus time, you can clearly see that in the beginning, when you pull the suture loop up, force is increasing with time. Then at some moment of time, the knot begins to slip, and it creates force to the maximum force. So the moment of maximum force is detected as the characteristic of knot slippage.
And then we continue the test for at least three more millimeters, or until the knot is completely untied, and we record the other force value which corresponds to the complete knot failure.
Q. Okay. Could you explain how recording those forces relate to the chart that's on the right-hand side?
A. So those recorded forces are presented in the table. Again, as you remember, we tested eight samples of each, eight samples of the coated suture and eight samples of the uncoated suture. And for each, we recorded two values of force, at the onset of slippage and at the complete knot failure. And those values happen to be recorded in

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kilograms. So the horizontal rows depict the corresponding values of the forces, and the very last row gives you the average values for the both eight forces.

As you can see, the coated and uncoated samples differed quite substantially, both at the onset of slippage and at the complete knot failure. At the onset of slippage, the coated samples showed knot strengths of about 3.3 kilo, and the uncoated samples showed over 5, 5.14 kilo. And at the same -- similar difference was observed at the knot failure, and the knot failure point, coated samples gave you an average strength of 2.5 kilo, and uncoated samples gave an average strength of 3.36 kilo. The differences are substantial, as later on confirmed by the statistical analysis.

Q. Now, just on this chart there's some plusses and minuses next to your averages. Do you see that in the bottom line?

A. Yes.

Q. Could you explain to the jury what that is.

A. In addition to showing the average values, this also shows the opposite of the variation, the fluctuations from sample to sample. So, as you can see, for example, from the first column, knot strength at slippage for coated samples, it was 3.3 plus/minus 0.95 kilogram, and for the second column, it was 5.14 plus/minus 0.67. This plus/minus gives you a good idea of the fluctuation of each and every number

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around the average value for the eight-sample set.

Q. Okay. Now, I think you testified earlier that there would have been a reporting error on the speed that the test was conducted; is that correct?

A. Yes. In my report, I described the speed being one value, and after it was pointed out to me at the deposition, I looked more carefully and found the actual speed of the test had a different one.

Q. Okay. Now, the difference in the speed of the test, did that change your opinions or your results at all?

A. It changes neither results nor opinion, can change nothing but just minor description of the test procedure.

Q. Now, Dr. Gitis, let me turn to the next test that you did which was your knot run-down test. Derek, could you put up 1366, please. And could you describe this test for the jury, Dr. Gitis?

A. Yes. Knot run-down test, even though again we see a suture loop, we see vertical orientation of the suture, but it's quite different from the two previous tests. In the knot run-down test, we still have a knot, but the knot is somewhere in the middle of the suture. Above the knot there is just single suture, and below the knot there is a suture loop. And the idea, the goal of this test is to measure slippage of the knot, run-down of the half hitch knot when you tension the suture up. So the lower end of the suture

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loop is wrapped around the stationary brass rod, and the upper end is clamped to the force sensor. Force sensor goes up vertically. And we measure knot run-down. We measure the force required to start knot going down on the suture.

Q. Okay, could you turn to Exhibit 1372. And could you, Dr. Gitis, could you explain what this is?

A. Yes. I'm sorry, we need knot run-down.

Q. Oh, I apologize, I apologize. It's my fault. 1369.

MR. SABER: Well, while we're on 1372, before you get it off, your Honor, I'd like to move to admit 1372.

MR. BONELLA: No objection.

(Defendant Exhibit 1372 received in evidence.)

Q. 1369.

A. Yes, 1369 describes the results of the test which we just saw the animation of. On the left we see is a plot of force versus time, and we see three examples for the uncoated suture and three examples of the coated suture. And you can clearly see that in the beginning when we were starting to going up and tensioning the suture, the knot was intact, and force was increasing. And then at some point the knot gave up and started going down, and force dropped. And while knot was sliding on the suture, we were measuring the -- we continued to monitor the force and measure knot sliding force.

Q. Okay, could you move to the chart, please.

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A. And the summary of the results -- actually, all the results are presented in the table. And, again, we tested eight samples of the coated suture and eight samples of the uncoated suture. And the last row on the bottom shows average results and data fluctuation, and you can clearly see that coated sutures had the run-down force of about 0.22 kilogram, and uncoated sutures had the run-down force of about 0.40 kilogram, which is almost a two times difference. It obviously looks like coated suture has better slippage characteristics, and so it requires smaller force to start knot run-down.

MR. SABER: Your Honor, I move to admit Exhibit 1369.

MR. BONELLA: No objection, your Honor

(Defendant Exhibit 1369 received in evidence.)

Q. Could you turn now to your setup for your friction test, Exhibit 1367. Could you explain this, Dr. Gitis?

A. Yes. In the friction test, there are two suture samples. Both of them are assembled horizontally. The lower one is assembled around X axis, and the upper one is assembled around Y axis, so they are perpendicular to each other. One of them is moved back and forth over the other, and we continuously monitor the frictional force, force to resist the relative portion of one suture over the other suture.

EXHIBIT 16

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.)
a Massachusetts Corporation,)
Plaintiff)
)
VS.) CA No. 04-12457-PBS
) Pages 683-904
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

JURY TRIAL - DAY SIX

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 14, 2007 9:03 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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take an hour just to sort of reorganize them.
MS. MALINOSKI: I think ours are still okay. I think there are some that still need to be redacted.
MR. TAMBURO: Actually, I think we may have worked that out. We'll talk about it, yes.
THE COURT: Okay, so I'm hoping that at the conclusion of my charge, I'll ask if you're both content with the exhibits, and then I will bring them in. And I strongly urge you not only to go through your own pile but go through the other side's pile, based on a bad experience that by accident -- and I believe it was by accident -- one of the paralegals from one side in one of my prior patent cases, worth millions, stuck in an exhibit which I had excluded. It was painful, which, of course, generated multiple post-motion issues, since the paralegal had just misunderstood my ruling and the attorneys hadn't caught it. So no one wants to be there. You put too much into this case. So just not only flip through your own pile, flip through the other side's pile, just to make sure you're roughly in agreement. If there may be a little a mistake on redaction, I don't care about that. Just make sure there are no big ones, you know, big problems that come in. And I will see you back here at twenty of.
MS. ELDERKIN: Your Honor, if I may, since plaintiff has the burden of proof, can I save part of my time

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to go after Mr. Saber? It doesn't seem --
THE COURT: No.
MS. ELDERKIN: No. So the defendant gets the last word?
THE COURT: Your side asked for that yesterday.
MS. MALINOSKI: No, your Honor, we did not ask for that. We were asking for rebuttal when we thought plaintiffs went first and then defendants and then plaintiffs because we have the burden of proof.
THE COURT: Well, why don't we -- you know, this is what I'm going to do. I'm going to stick with the way I always do it in Federal Court here: You go first, you go second, and that's it. We don't usually have rebuttal in civil cases. It's done in criminal where the prosecution goes first. So that's how we're going to leave it.
MS. ELDERKIN: That's fine, your Honor. Thank you.
(The luncheon recess was taken, 12:50 p.m.)
AFTERNOON SESSION (1:45 p.m.)
THE COURT: I make it a practice of handing out the verdict slip, which there really isn't much here, before the closing arguments, and so I hope you've all had a chance to look at it.
MS. ELDERKIN: The verdict form?
THE COURT: Everybody approves of it?

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MS. ELDERKIN: Yes.
MR. SABER: It's fine, your Honor.
THE COURT: All right, the next thing is, have you had a chance to go through the exhibits?
MR. TAMBURO: Yes.
MS. MALINOSKI: Yes, your Honor.
THE COURT: So let's bring the jury in. As I mentioned, Arthrex will go first, and I'll give you a five-minute warning, and I won't yell if you go a little over but just a lot over.
MR. SABER: I didn't get a chance to practice it, so I'm not quite sure.
(Jury enters the courtroom.)
THE COURT: I've asked Mr. Alba to hand out a copy of the verdict form. Obviously, at the end, we'll only want one verdict form, and it needs to be unanimous. However, I thought you should take a quick look at the question you'll be asked to answer before you hear the closing arguments.
We do the closing arguments in the reverse order of the opening statements, so that means that Arthrex and Pearsalls will go first, and then plaintiff will go second -- that is, DePuy Mitek -- because it has the burden of proof. Each closing argument will be about forty-five minutes. At about forty minutes, I will give them a five-minute warning, and at about forty-five minutes, the hook.

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(Laughter.)
THE COURT: After that, I hope to take a brief break, mostly because people can't concentrate for much more than an hour and a half at a time. And then I'm hoping, if everything goes according to plan, to get you the charge today. I will leave it up to you to see whether you're too exhausted and just want to go home and start afresh with deliberations tomorrow or whether you want to get going today. So why don't I not talk anymore except for the attorneys to talk, and we'll start with Mr. Saber.
MR. SABER: And God knows, attorneys like to talk. If you can just give me a moment to get organized.
CLOSING ARGUMENT BY MR. SABER:
MR. SABER: Let me begin with just a couple of thank-you's. First, I'd like to thank Ms. Elderkin and her team. You don't really imagine how difficult these things are for the attorneys, and when you have a situation where you can't talk to the other side, it makes this really, really difficult. But that has never been a problem with working with Ms. Elderkin and her team, and I hope she'll say the same about us. It's made it just a little bit more pleasurable and a little bit easier than it otherwise would be. So thank you very much.
And I certainly want to thank my team, particularly Sal, who of course you've heard from quite a bit, and I

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couldn't do it without him. And Rebecca, Derek, and Ashley, they're all great. I can't do this by myself. You've seen me the most, but it's really all of us. Mr. Lawson, John, again, thanks so much for being here reporting. I'm really going to miss you guys.

I wanted to thank the Judge. You don't know how lucky you are to have a judge like Judge Saris.

A JUROR: We do.

MR. SABER: She's terrific. Well, good, I'm happy that you feel that way because I think I speak for both Ms. Elderkin and myself. She's a terrific judge. She kept our feet to the fire so we got you out of here perhaps a little bit quicker than we otherwise would have done.

But my biggest thank is to you, to you, the members of the jury. Our system of government simply doesn't work without you. I've been called for jury duty three times, but I've never made it on there. I'd love to do it as a lawyer, but I can tell you just how much we appreciate everything. I hope you're going to vote for our clients, but whether you do or you don't, I really do appreciate all your effort and all your concentrations that you've given here today.

Well, in my opening statement a little over a week ago, I told you that I was going to give you a tour, and I think I took you through what we thought the evidence would be. And I asked you an important question at that time.

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There was a term that I asked you to keep in your mind, and that term was "suture handleability." I asked you to keep that term in mind because I told you through my tour that the evidence would be that the effect that coating has on suture handleability would be substantial and important.

I told you that I expected that we would present overwhelming evidence to you that the FiberWire coating has that important and substantial effect on suture handleability. I think I told you that I didn't think you'd hear a lot from DePuy Mitek about that, that they wouldn't really challenge what we were saying about the importance of suture handleability; they wouldn't have their own evidence to try and change that. Rather, what I thought you'd see from DePuy Mitek were just some attacks on what we did, you'd see a lot of those, and you'd see some evidence, but not on suture handleability.

And I told you that if you felt after hearing the evidence that we were right, that I would be back at the end of the case and ask you to return a verdict in favor of the defendants. I hope I satisfied what I said I was going to do, and I am back here asking you to return a verdict for the defendant.

Well, that time has now come to talk about that and for the next thirty or forty minutes or so, I'm going to try and summarize the evidence in which we believe shows you,

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without question, that the FiberWire coating affects suture handleability and pliability.

As you listen to these closings and as you deliberate, I ask you to consider this: Which party gave you the evidence to that issue? Which party gave you the tests? Which party told you about the known teachings in the field? Which party told you about the tried-and-true coating process that has been used for over twenty years that's used to put that coating on FiberWire? Which party brought you evidence, not from one but from two or the surgeons, the very people who use the sutures? Which party presented you with a suture expert that has spent his entire career working with sutures? I believe that the answer to all of these questions, every one of them, is Arthrex and Pearsalls.

Now, where was DePuy Mitek in all of this? With all the resources of Johnson & Johnson, all $53 billion, with the legion of people that you saw here in this courtroom, why didn't they present you with a single test? Why didn't they tie you a single knot? No pliability tests, no knot run-down tests, no friction tests, no knot security test, no tissue drag test, no chatter test -- not a single one. Why didn't they bring in an orthopedic surgeon to tell you that coating isn't a big deal? Nothing. You got nothing from them.

Well, you know, we know it's certainly because they don't know how to do tests (Sic). After all, Ethicon is the

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largest suture manufacturer in the world. They even have Dr. Gitis' testing machine sitting right there in their offices in New Jersey. They show it off to their customers. Dr. Gitis told you about that. But they couldn't run a single test for you, not a single test comparing the coated and uncoated FiberWire on that machine that Dr. Gitis sold them.

I submit there's a very, very simple reason that they did not submit a test. It's really simple. They knew if they had run the test, it would have shown exactly what Dr. Gitis and Ms. Willobee's tests showed; that the FiberWire coating clearly and demonstratively and materially affects suture handleability and suture pliability.

You know one thing for sure: DePuy Mitek certainly can't say that they have any real evidence on this very important critical issue to support their case.

Well, let me tell you a little bit about the evidence that Arthrex and Pearsalls did submit. You heard from Dr. Burkhart. He was one of the orthopedic surgeons that came in last week. I hope you remember him. He's a surgeon that consults for Arthrex. He told you how important it is in orthopedic surgery -- remember he came up and he showed you what an orthopedic surgeon does? -- how important it is that the suture handle well. He told you about the need to have that suture maneuver well in surgery. He told

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you about the speed that you have to operate in orthopedic surgery. He told you about all those manipulations, all those different things that you have to do in surgery. He told you all of that.

But he told you, most importantly, he told you that the reason that FiberWire, as well as other braided sutures, meets those needs is because they're coated. He told you just how important it was for FiberWire to be coated to improve suture handleability and suture pliability. He wouldn't use a braided suture that wasn't coated. Why? Because he knows how important it is in surgery.

Now, I know he thinks FiberWire is the best one, but what he told you: You've got to have it coated, right from the horse's mouth.

One more word about Dr. Burkhart. You know, they made the point he's the one who wrote that E-mail about the killer idea to Mr. Grafton. And he came in and he said, "Yeah, I wrote it, you bet I did," right? And I asked him, I said, "Well, Dr. Burkhart, when you said that that was a killer idea, the thing that led to FiberWire, were you trying to say you didn't have to have it coated?" He said, "Are you kidding? Of course it had to be coated. It's a braided suture." And he said, "Mr. Grafton and I talked about why you have to have coating on a braided suture."

This killer idea, that's how they're going to try

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and convince you they're right that it didn't need coating? It's not the evidence. Dr. Burkhart told it to you. Mr. Grafton in that video that was read to you, he said it as well.

As I say, Dr. Burkhart wasn't the only one who said that the FiberWire had to be coated. Mr. Grafton said it in that deposition. And, you know, there was another inventor on that FiberWire patent, Mr. Lawson Lyon, who came here from Taunton, England. I love Taunton. It's right near where I grew up. The two inventors, they told you that FiberWire had to be coated to achieve a good knot run-down and the other handling characteristics.

But there's more. Do you remember Mr. Lyon told you that he wrote down in the FiberWire patent? They said in that patent that the coating is there to fill in the voids in the braid and to optimize the knot run-down.

And Arthrex says that coating, what it does, coating. Remember that important document sheet, the one that's approved by the FDA? Derek, could you throw up 1106. It's on. I can't see it. I hope you can. Oh, great, thank you very much. I appreciate it.

This is the Important Product Information: "The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through the tissues," FDA-approved statement. That's what the evidence shows.

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Now, Arthrex, why are we here? They're the innovative company. They're the ones who were first to market with a high-strength suture. DePuy Mitek, they were last in the market. Arthrex was the one who has a patent covering their high-strength suture product. The '446 patent doesn't cover Orthocord, doesn't cover their product. All I know is that DePuy Mitek got their assignment of this patent just a few weeks, just a little bit before this lawsuit was filed.

But I do know one other thing. You'll have to ask yourselves what are going on, but I do know this: Before they came up with this plan to file this lawsuit to get this patent that doesn't cover their product, right, they wrote a marketing report. This is after FiberWire came out. And what did they tell you in that marketing report? This is before they thought about suing us. Talking about Arthrex, "They released several competitive suture anchors, shoulder instrumentation as well as a novel suture, FiberWire." That's what DePuy Mitek said before they started this lawsuit, before they had the idea to just get a patent and sue us. It's a "novel suture," their words, not mine.

Now, I want to go back to Mr. Lawson. He told you much, much more. He told you about how Pearsalls developed its coating process over twenty years ago. He told you about how the sutures go through that bath, not once; it goes

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through twice. He told you that the silicone coating, you've got to go through those pads to get out the excess coating. You have to go through the oven. He told you exactly why the oven is there. The oven is there to cure -- remember that word -- it cures it on, it bonds it on. You heard all that information, both from Dr. Mukherjee and Mr. Lyon. Now, Mr. Lyon didn't know the chemical name of it because it's not what he does, but he told you how it cross-links it, it bonds it right on. That's what the oven's there for. That's the process it goes through. It's the bath, the pads, and the oven. That's the coating process.

Now, they're trying to just create a little sideline about that, and we'll talk about that in a little bit, but the one thing that there's no dispute about: That's the coating process.

And now there are the tests, the tests and the tests and the tests. You heard from Ms. Willobee. She did that knot run-down test. She's the director of research for Arthrex. She explained exactly what she did in that knot run-down test. She told you how repeatable her results were, and she told you that it took more than twice as much force to get that knot on the uncoated sample of FiberWire to move. She told you that.

And then there was Dr. Gitis who came here from California. He didn't have the California accent, but he

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came here. He's the man who sells testing equipment to Ethicon. He's the man that Ethicon has hired to do its suture testing. He's the man who did test after test after test for us. He's the man who told you that after all his tests, each one of them showed that the difference between FiberWire coated and uncoated was large and statistically significant.

Now, I'll tell you, Dr. Gitis isn't perfect. He made mistakes. But I'll tell you something else about Dr. Gitis: He's an honest man. He came in here and he fessed up to his mistakes. He explained them to you, and he told you why, at the end of the day, they didn't change his results. That's what honest men do, and that's what Dr. Gitis did.

And one last thing about Dr. Gitis. You remember Mr. Bonella, he asked him some questions about his friction test; you know, the one where there was some corruption of the data. He explained to you why the results were still okay. But Mr. Bonella was kind of tough on him. And what did Dr. Gitis tell Mr. Bonella? "I offered to you that I ain't sure on the results." This is about his friction test. "If you doubt it, I will redo it free of charge. You fought it. You were against redoing the test."

Now, why was DePuy Mitek against redoing the test? I suggest it's the same reason that they didn't do a single

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test on their own: They were afraid of the results.

Well, there are even more tests. Arthrex asked Dr. Burks, the second orthopedic surgeon, to do some subjective tests between uncoated and coated FiberWire. And that's what he did. He did his report. Remember, he did that blind test for his report. I'm going to talk about his deposition in just a little bit. He did the blind test for his report. He knew one was coated and one was uncoated. He didn't know which one it was.

He got it right. He said Suture A -- it was Mr. Gitis who sent it to him -- those were the coated, more smooth, tied better. Suture B, the uncoated, it wasn't as smooth, it didn't tie as well. He got it right.

Now, they tried again in his deposition, and I'll talk to you a lot more about that in a minute, but once again, he got it right each time.

Now, how do we know that, you know, because it was all kind of a little here and there? You remember he filled out a little sheet? I don't think there was a lot of testimony about it, but he said it in his deposition. He had 284. Remember there was 284, 285, and 286. 284 he said was uncoated. 285 and 286 he said were coated. Well, we read some stipulations in to you earlier in the case. I'm going to summarize them, but 284, that's the one that didn't go through the bath, didn't go through the pads, didn't go

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through the oven, uncoated. 285 and 286, those were the same as the commercial FiberWire. They were coated, just like Dr. Burks got on his sheet. Got the uncoated and the two coateds. I'm going to talk to you a little bit more about that so-called test in just a few minutes.

And, finally, let me talk a moment about Dr. Mukherjee. He was our suture expert. He's the person who teaches the doctors about sutures, how they're made and what they do. He's the one who worked for the suture manufacturer. He's worked for Davis and Geck for those thirteen years working with sutures virtually every day. He's the one who wrote the chapter in the book about sutures. And what did he tell you? He went and looked at those teachings of the suture art, and he left no doubt that those teachings are used to improve suture -- without question, that coatings are used to improve suture handleability and pliability.

I'm not going to bore you with a lot of those. I'm just going to read you one from an Ethicon patent. It said, "Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires surface coating to improve the tactile smoothness, pliability, and tieability performance of the suture so it passes easily and smoothly through tissue during operative procedures."

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There are a lot more like that, but there's no question: Everyone knows that's why you add coating to braided sutures.

Arthrex and Pearsalls, we gave you the evidence. We're the ones who told you why FiberWire is coated. We're the ones who told you that the coating is applied to FiberWire and how it's done. We're the ones that explained the teaching of the coating suture arts. We're the ones that brought in the orthopedic surgeons. We're the ones who showed you test after test after test. We're the ones who gave you Dr. Mukherjee, who told you exactly what those tests mean, and left no doubt in anyone's mind.

It's not what you got from DePuy Mitek. I submit it wasn't a whole lot of evidence, and it certainly wasn't about what coating does. You didn't hear very much from them about what coating does. Instead, you got a lot of tricks, you got a bunch of irrelevancies, and you got a lot of testimony from a woefully unqualified expert. Well, at least one that's unqualified to testify about the effects of coating on sutures.

Now, DePuy Mitek never challenged our evidence that it's critical to surgeons that there be good knot run-down, that the suture run through tissues well. No challenge. They never challenged our evidence that it's universally known that coating is put on the sutures precisely for these

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reasons. Well, how could they? Patent after patent, most of them by Ethicon, say so. Witness after witness at their depositions said so. Document after document written by Ethicon where DePuy Mitek said so.

I'm just going to read you a couple of those deposition testimonies that we read in earlier today. These are DePuy Mitek and Ethicon people, okay? "Why is there a coating on the product?" This is to Gary McAlister from DePuy Mitek. "It makes the handling much better. It is my understanding that's why coatings are put on there. It will tie better, it will slide better. They call it the hand, it improves the hand."

Mr. Koyfman, Ilya Koyfman. There was a document, they were talking about the document. "Coatings provide the lubricity necessary to achieve smooth tie-down and knot slide performance. Do you see that? Yes. What do you mean by that sentence? As I mentioned previously, it is important to have the smooth when the surgeon makes knot. That means that the tie-down in the suture knot has to slide without hesitating. It has to slide smoothly. What do you mean when you say the coatings provide lubricity necessary to achieve these characteristics? Lubricity means the introduction of friction, so if you don't have it, you're not going to have a smooth tie-down. It's going to be a raspy suture. Why do coatings provide the lubricity necessary to achieve a smooth

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tie-down? Because the main purpose of coating is to provide the lubricity to reduce the friction. And what's the basis of your statement? Based on lots of experience and testing of existing products."

That's why they didn't bring in someone like Mr. Koyfman to testify, because he knew the truth, and they wouldn't bring him in because they didn't want you to hear it. Well, we put on the witnesses, and they told you the truth.

Now, let's talk a little bit about Dr. Brookstein. Time and time again he said he made no effort to look at the suture patents and the suture literature to see what coating does. He didn't know if any of it was true. He didn't recall if it was true.

Now, finally, he said, "Oh, no, no, no, no, those teachings, those don't go to generally." Remember he said that to you? He said, "No, no, no, that's just about a specific suture. That's just about a specific coating."

That's not what I just read to you from Mr. Koyfman. That's not what I just read to you from the Ethicon patent. But it's Dr. Brookstein's excuses. Dr. Brookstein, he's not an expert in sutures, but he can tell you, "Oh, no, no, no, that's just about this one kind of suture. That's just about this one kind of coating." It's not what the document says.

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Let me boil down DePuy Mitek's argument. It's really simple. In a nutshell, DePuy Mitek's argument is that somehow FiberWire is the only braided suture ever created that does not add coating to improve suture handleability. Just to say that just shows you how silly it is. Let's use a little common sense. Do you really think that Arthrex and Pearsalls put coating on their FiberWire just for the heck of it? Of course not. They put the coating on FiberWire for all the have you reasons: to improve suture handleability and pliability, just like everyone else, just like Ethicon, just like DePuy Mitek, and just like those tests show.

So what does DePuy Mitek do? They don't put on evidence. They try to cut up our experts. They sure did that. They have to do that because they didn't give you a single test. With all that money, with all those people, with all that equipment sitting there in New Jersey, they didn't conduct a single test. They didn't tie a single knot, zero, nothing.

Well, their attack on our experts utterly failed. They couldn't disagree with Ms. Willobee's results. They couldn't disagree with what she said, so they tried to say, well, she doesn't really know what she tested. That's their answer. Well, she said she tested the coated and uncoated FiberWire. She said Mr. Grafton gave it to her. And, now, you heard that Mr. Grafton asked Pearsalls to do the coated

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and uncoated from the same production run, and you heard Mr. Lawson Lyon come in here and said, "Yeah, they told me to do that. I directed my people to do it, and that's what we did," right? You ask, what's going on here? "Oh, we don't know what it is. We don't know exactly what it is." That's what you say when you don't have any evidence.

Dr. Gitis, he did a lot of tests. Now, they want you to believe that every test he did was flawed. They don't say that the numbers don't show what he says. They say the tests were flawed. Why? Because they don't have any evidence, no tests, not a single knot.

And this is the same Dr. Gitis who did the suture testing for Ethicon and his equipment they show off. He's good enough for them when they want to do the business, when they want him to test. Only now, when his evidence devastates their case, did he somehow overnight become an incompetent. I think you know what's going on here. I sure think I do.

I'm not going to go through all their criticisms of Dr. Gitis. I just want to talk about the pliability one. Dr. Brookstein said he did it the wrong way. Dr. Gitis said he did it the right way. But the evidence shows -- I'm sure you didn't understand any of their explanations. Neither did I, to be honest with you. But the evidence, the evidence shows that Dr. Gitis used the same pliability test that he

used for evidence. They never came in and said that that was wrong. You didn't hear an Ethicon person who came in and said, "Oh, no, no, no, that's not the test that Dr. Gitis did for us." They never said it because it's true. It was good enough for Ethicon when they were running their business; it should be good enough for us when we're trying to prove the point. I think you know why they're doing those attacks.

Let's talk about Dr. Burks. They're trying to use him. They can't deny that he got it right in his report, okay, where he was given the blind sample of the coated and uncoated, and he correctly identified the coated ones as being smoother and better knot-tying knots. Remember we had Suture A. Dr. Gitis said that was the coated and that was the better one. Suture B was the uncoated. That was the one that didn't test as well.

Well, they couldn't answer that, so they tried a trick at his deposition. They brought in three samples. But they wouldn't tell him whether they were all coated, whether they were all uncoated, or whether they mixed. "We're not going to even tell you that." They didn't do a fair test. They didn't do the one that says, "We've got one that's coated and one that's not coated. We won't tell you which one. Do it blind. We're not even telling you if we gave you coated or uncoated."

You know, this is like trying to pick it out of a

door, a trick. But you know something? The trick didn't work, right? Dr. Burks got it right. I read you that stipulation. It matched his sheet that he put on. He got it right.

So what are they left with? Their trick didn't work. So they're saying, well, you know a couple of times he says the difference was subtle, it was a subtle difference, it wasn't a big difference. Oh, you see, it can't be important, it was only a subtle difference.

Let's look at what he actually said, by the way. He said, "The difference wasn't so great that if I tried it a hundred times, I might not get one wrong. I wouldn't bet my children's life on it," right? "It's not like the difference is rocks and water." That's what he said.

But let's talk about something a little more fundamental. Now, this is surgery we're talking about. Remember I talked about surgical precision in my opening. This is no analogy. This is surgery. They never asked Dr. Burks if the difference, that subtle difference, the rocks and water, not betting on your kids, that was important in surgery. But Dr. Burkhart told you that differences matter in surgery. Dr. Mukherjee told you that those small differences were critical in surgery. This is surgery. It saves time, and it insures a better outcome.

Do you want to hire a surgeon who tells you,

particularly if something goes wrong in the surgery, "Well, you know, I used something pretty good, but I didn't use the better one"? This is surgery. Doctors work with surgical precision. You've got to use the one that's even a little bit better.

Well, I just want to do one last thing on here. I want to put his testimony in perspective. I want to show you just a little snippet of the video from Dr. Burks, the one where he was tying 284, the uncoated suture:

"I'm tying 284. Sal, put your finger on this just a second so it doesn't slide around on me. Just hold it down."

Did you hear what he said? I don't know if you caught that. He said, "Sal, put your finger on this just a second so it doesn't slide around on me. Just hold it down." He didn't have to do that for the coated ones, but he had to ask Mr. Tamburo to help him. Well, I'll tell you something: Sal's a great lawyer, I love him, but if he wants a new career, I guess he can go around with Dr. Burks and hold down his surgery for him when Dr. Burks is using the uncoated sutures. That's what their evidence comes down to: "Sal, could you hold it down for me." He even needed help to get the uncoated one down. Subtle difference? You decide how important that subtle difference is.

Let me talk a little bit about Dr. Brookstein. We

have no doubt that Dr. Brookstein knows about braided textiles. He knows a lot about that. But he knows next to nothing about sutures, and he knows absolutely nothing about the effects coatings have on sutures. Let's talk about his CV. There's not a single article about sutures, not a single patent on sutures, not a single description of a project that was about sutures, right?

Now, he did work on one. He worked on one, oh, I don't know, fifteen, twenty years ago, only one in his professional life years and years ago. Now, at the time of his deposition, remember I asked him, "Well, did that involve coating? I don't even remember if the thing was coated."

Now, I tell you, at his deposition now he had an epiphany. He now knows it was coated. But if you listen carefully to what he said, Dr. Brookstein told you that it was U.S. Surgical that did the coating and sent it to him, right? He was hired for his braiding experience. Remember I asked him, I said, "Don't you assume that's why you were hired, for your braiding experience?" He said, "Yeah, that's why I assumed I was hired." I have no doubt he's a good braider, but knowing about sutures, he's not the guy. Knowing about coating, he's definitely not the guy.

The simple fact is, at his deposition I asked him and he said, "Isn't it the fact that everything you know about suture coating and its impact on suture properties you

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learned in connection with this case?" Now, he tried to back away from it here in court, but that's what he said: Everything he knows about suture coating and its impact on suture properties he learned in this case. That, members of the jury, that's not a suture expert. With all their resources, with all those suture experts they have over at Ethicon, you'd think they'd come up with someone better.

Now, I think we know why Dr. Brookstein was the one they chose. They didn't want someone who really knew it. They had to find someone else.

I want to talk a little bit about what Dr. Brookstein did talk about. Remember he made that big pitch that FiberWire is heat stretched. You heard a lot of testimony from them about that. I've got to tell you the truth, I'm not really quite sure why they put it in, what it really goes to. It wasn't real clear. I'm sure Ms. Elderkin will tell you, but I was -- and sometimes they had this argument, well, you know, when you did this suture test, you didn't isolate how much came from heat stretching and how much came from coating. You know, he did that one and two. I mean, they had some arguments about that, so I think that's where it's going, though I can't tell you I'm really sure. But I will tell you this: The argument is nothing more than a smoke screen because they don't have the tests, they don't have the evidence.

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The simple and undisputed fact is, those wiper pads in the oven are part and parcel of the coating process. Mr. Lyon explained that very, very clearly. Do you remember he told you, he told you that those pads, those rubber pads wipe off the excess coating. And the oven, it bonds the coating onto the suture, dries the coating, and evaporates the solvent.

Brookstein, at first he said, "Oh, no, coating's not part of the process. Oh, no, it's not part of the coating process." Then I said, "Didn't I ask you that very question at your deposition?" He said, "Oops, I guess it is part of the coating process." Right?

But there's more about Dr. Brookstein. There's more about it. Do you remember he submitted a declaration in court and I asked him about it? I want to read what he said under oath to this Court: "I personally observed and studied Pearsalls' coating process for FiberWire during inspection of Pearsalls' facilities in January, '06. FiberWire is coated by passing a braid of PET and ultra high molecular weight PE which has been dyed and scoured through a bath of Nusil 2174 polymer and Xylene solvent at a rate of 20 meters per minute. Xylene is not a coating. Rather, Xylene is a solvent that dissolves the polymer so it can adhere to the FiberWire braid. After passing through the solution, the coated FiberWire is passed through pads which are compressed

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together to wipe off excess coating. Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent. That process is then repeated."

Did you hear "heat stretched"? That's what he said under oath to this Court. No, you didn't. I asked him about that, and he said, "Oh, no, no, no, I said, I said, well, the pads are compressed together." Of course they're compressed together. That's how you've got to get the excess coating off. He says, "Oh, I guess I must have missed that." The whole centerpiece of their case: "I must have missed that."

I think you know what the truth is. They just made it up now.

But let me tell you, let's say he's right. Let's say we don't have to get into a debate. Let's say he's right there's some stretching there. You know, Mr. Lawson Lyon told you about those roller pads, the ones that aren't used. He explained exactly how you stretch. You have those roller pads, and you have another set, and you put them at different speeds. Even Brookstein had to admit that FiberWire doesn't go through that. They never disputed that that's what heat stretching is all about.

But let's assume he's right. Just for a minute, let's assume he's right. Is there any evidence that you don't coat? Is there any evidence that you heat stretch sutures instead of coating them? Not an iota of evidence.

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Is there evidence of the opposite, that even though you heat stretch sutures, you still have to coat it? Yes. Dr. Mukherjee this morning stood up above that stand, and he told you about his thirty years experience, about stretching those fibers. He said: Of course you have to coat them. They're all coated if they're braided because what heat stretching does and what coating does is not the same thing.

You know, I guess you really come down to their argument: Oh, it's not the oven. Well, maybe it is the oven. Oh, it does stretching. Well, you know, maybe it does, maybe it doesn't. Right? I think what they want us to do is just put the sutures into that bath, don't wipe it off, don't cure it on. That's coating. That's coating to them. But that's not the evidence. The evidence is, it's all part of the coating process.

And, more importantly, the evidence is, regardless of whether this irrelevant debate is true or not true, you have to have the coating. But that's the kind of arguments you raise, those are the irrelevancies you raise when you don't have the evidence, when you don't do the tests, when you don't tie a single knot. That's what you try to do.

So what are we left with? We're left with Dr. Brookstein's microscope, another one of the tricks. He switched the pictures. He didn't like the ones from his original report so he gave you different ones. He said,

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well, you can see them better. He switched the pictures. He used different magnification for the different pictures, and he used different angles. Does that sound to you like it's playing fair? I don't think so. It sounds like a trick, just like what they tried to pull at the deposition.

But, more fundamentally, he used the microscope for a purpose that's totally improper. Now, he came up and said it's proper, but he also told you he had never used that standing electron microscope for a suture before, never. Now, he said he's been using it for thirty years. He only had a couple of examples from twenty or thirty years ago. He used it for bridges, he used it for air beams. I may have the words slightly wrong. I didn't have time to get the exact quotes. But they weren't things that were like sutures, right? That's what he used it on. He never used it on a suture. And yet he's coming in and saying, "Oh, that's absolutely proper. Oh, yes, no question about it, the different angles, different magnification, absolutely proper."

Well, what's the evidence from people who actually used these things for sutures? Dr. Mukherjee came in. He's the one, he said, "Do we use it for sutures? Oh, yes, used it many times for sutures. Thirty years I've been in this business." And he told you exactly why it's improper. He said, "We use it. We use it because there's damage to the

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suture so we need to examine it. But for the coating, you wouldn't use it, you know, it's a colorless coating." He said, "You know, we sometimes tried to see. Sometimes someone would see something, someone wouldn't," right? And I asked him, "Would anyone knowing anything about this business, would they use this microscope for this purpose?" He said "absolutely not."

Now, I don't know in my heart of hearts whether Dr. Brookstein knows that or not. God knows, he doesn't know very much about sutures, but he's either trying to pull one over on you, or he just doesn't know.

Dr. Brookstein, frankly, he's a trickster, right down to his little card trick. Do you remember that card trick he did and he glued the cards together? You know, that's not what silicone does. Silicone is slippery. It doesn't glue. It's not super-glue like he used on his card trick. It's a trick, just like the deposition, just like the microscope. It's tricks.

Now, I've got to tell you something about Dr. Brookstein. I actually like him. And I've got to tell you, the next time I go to Foxwoods, I'm taking him with me. He'd be great there. But for a suture expert? No way. I'll take Dr. Mukherjee every day of the week and twice on Sunday. He's the guy who knows about sutures. He's the guy who spent his life on it. He didn't come in and give you

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card tricks.

But they don't have any evidence, DePuy Mitek, no tests.

THE COURT: It's about the five-minute mark.

MR. SABER: I'm going to make it. So the last-ditch effort, what do they do? They tell you that the coating can't materially affect the basic and novel properties because the '446 patent says you can add a coating. Well, the Judge will tell you, you can't just do that; you have to look to all the evidence. You can look to the patent, but you've got to look to all the evidence. So that doesn't get them there.

In any event, there was all kinds of evidence about what this patent teaches. You heard they like to use a couple lines. We went with other lines. We showed that this was a patent that teaches you get all the advantages without using coating, just from the mechanical blending. It's a patent that described that there were problems in the prior art -- that's a fancy word that means things that came about -- with coating, right? It's a patent that says, well, maybe you can add it in, but if you can, you want to eliminate it and save the expense and the problems, right? That doesn't sound to me like a patent that's teaching you to use coating. If anything, it sounds the other way.

Frankly, ladies and gentlemen -- ladies, I guess

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there are no gentlemen -- frankly, I don't think you can decide the case just looking at the patent. I think you've got to look to the evidence.

Well, what's the last thing that they're going to say? They're going to say that the improvements, that Mr. Grafton said, "Oh, see, I get all my improvements just from blending the things together." It's not what he said. He talked about knot security, you improve knot security by doing that. But the other factors, Mr. Grafton told you, "We knew we had to have a coating." Mr. Lyon told you, "We knew we had to have a coating." Dr. Mukherjee told you, "Absolutely, you have to have a coating." That's the evidence. The evidence is: You've got to have the coating. It's critical, it's absolutely necessary, and you can't sell the product without it.

Well, members of the jury, I end where I started. Who gave you the evidence, who gave you the tests? Who told you about what the art teaches? The answer is clear and demonstrative: Arthrex and Pearsalls gave you the evidence. They gave you the evidence that shows that coating materially affects the basic and novel properties of the '446 patent. And if you agree with me, and I trust that you will, when you go into that jury room, I ask that you check the box that says "No infringement," and that's a vote for the defendants in this case, and I ask you to do that.

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Thank you very, very much for your patience, and the good news is, this is the last time you have to hear from me in this case. Thanks again.

THE COURT: Why don't we stand up and stretch.

(Pause.)

MS. ELDERKIN: Your Honor, I'm using this board. I'll give you a copy. It's just the novel and basic properties.

THE COURT: That's fine.

CLOSING ARGUMENT BY MS. ELDERKIN:

MS. ELDERKIN: Members of the jury, this case is about this patent and the special invention in it to a special braided suture, a composite suture that had special properties due to the special materials from which it was made. The case is about the contribution that Dr. Mark Steckel and his co-inventors made to the world of sutures, and it's about whether Arthrex is using the patented invention without Mitek's permission. That's the issue that you're being asked to decide, and as Judge Saris has already handed you the jury verdict form, you're going to be asked if plaintiff DePuy Mitek has met its burden of showing to you that FiberWire infringes this patent.

I'm going to talk to you about the evidence that you've heard, and I plan to do it in a calm way. I'm not going to resort to attacks on Arthrex, or on its witnesses,

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or on its lawyers, because I don't have to. The evidence supports our case, and I'm going the tell you about the evidence.

Now, you didn't see a lot about the claim language in this case that's on screen now. You heard at the beginning of the case that the claim is the language that draws the boundaries about what is protected by the patent, what is the protected invention? And you didn't hear much about this because there's really no dispute about most of these terms, so I'm just going to talk through them very quickly because it is our burden to show you that FiberWire meets each of these things in the claim.

The first thing the claim says is a surgical suture. Of course, there's no dispute that FiberWire is a surgical suture. We'll skip over consisting essentially of.

The next thing the claim talks about is that this is a homogeneous braid -- that's a braid of two different components -- composed of a first and a second set of continuous and discrete yarns, in a sterilized braided construction, wherein at least one yarn from the first set is in direct intertwining contact with the yarn from the second set. And you've heard all about that for FiberWire. It has two different types of yarns, and they are braided together so that the yarns are in direct intertwining contact.

There's a first set of yarns, as described in the

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next element here in the claim, there's a first set of yarns made from a first type of material, and there a bunch of different materials listed in that claim. The only one you really have to pay attention to is PE, the one that we've highlighted in orange, because that's the material that's in FiberWire.

Then the claim says there's a second set of yarns, and it describes the materials from which those second set of yarns can be selected. The only one you have to pay attention to here is PET because that's also the material that's in FiberWire.

And then, of course, the claim says optionally a core. FiberWire does have a core. So everything in this claim that I've just clicked off is in FiberWire. You heard no dispute. Mr. Saber didn't even mention this language in his closing argument.

The argument really hinges around this language "consisting essentially of." And you've been instructed in the beginning, and you'll be instructed again by Judge Saber, that what that means is that this claim can cover a suture, even if that suture has something in addition to what's recited in the claim, something like a coating, so long as that something additional, a coating, does not materially affect the basic and novel properties of the invention.

Now, it's important for you to keep a few things in

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mind when you consider this. The question is not, do coatings affect sutures? That's not the question. The question is not, does the coating on FiberWire affect FiberWire's properties? That's not the question, and you heard a lot about that, but that's not the question for you to decide. The question is, does the coating on FiberWire have a material effect on the basic and novel characteristics of the Hunter '446 patent invention? And Judge Saber defined those basic and novel characteristics --

THE COURT: Judge --

MS. ELDERKIN: Saber? Oh, Lord.

(Laughter).

MR. SABER: I like the ring.

MS. ELDERKIN: Wow! You should throw something at me.

THE COURT: It's a long week.

MS. ELDERKIN: I do apologize, your Honor.

Judge Saris defined the basic and novel characteristics for you, and this, this is where your focus needs to be. And, as I recall, you didn't hear any mention of this in Mr. Saber's argument, but this is where the focus has to be: Does the coating on FiberWire affect these things?

Now, when Judge Saris first described these or defined these basic and novel characteristics for you at the

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff

-VS-

ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants

CA No. 04-12457-PBS
Pages 1 - 142

JURY TRIAL - DAY ONE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., and LYNN A. MALINOSKI, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 6, 2007, 9:10 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
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the material. It's smoothing out the surface of the braid. You're pulling on that braid, so you're pulling it out, you're making it denser, and you're smoothing out some of the bumps on the surface of the braid.

So the FiberWire, commercial FiberWire that Dr. Burks tested has a coating on it, but it's also subject to this heat stretching, two things that might conceivably make the FiberWire smoother.

The uncoated FiberWire that Dr. Burks tested was taken off of the assembly line before it ever goes into the coating bath, so the uncoated FiberWire that he tested never went through the heat stretching, never went through the coating. So there are two things that could have affected the surface of the suture and made them smoother, made them smoother so that Dr. Burks could detect a difference between the treated commercial FiberWire suture and the untreated, uncoated, unheat-stretched suture.

So how do we know which one of those things affected the smoothness, and how do we know whether the coating alone affected the smoothness of the suture, affected the properties of the suture in any kind of a material way? Well, there's a second thing about Dr. Burks's testimony that's important and that may help you to put the answer to that question into perspective. You'll hear Dr. Burks say in his testimony that even though he could tell the difference

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between the treated, coated, heat-stretched suture and the uncoated, unheat-stretched suture, he could tell the difference, but the differences were subtle, he said. He said they were pretty close. He said that "We're not talking rocks and water here."

So even though the commercial FiberWire has two things that can affect how smooth the surface of the suture is, coating and heat stretching, the difference between that commercial suture and a suture that didn't have a coating was still subtle, or pretty close.

THE COURT: You need to start finishing up.

MS. ELDERKIN: Okay, yes, your Honor. So the evidence shows that even with two treatments of FiberWire braid, the difference between them is subtle. So if the difference with two treatments is subtle, the difference with only one treatment, just coating, would have to be less than subtle.

Dr. Brookstein will explain that FiberWire Suture is still a braid of PE and PET, with both of these constituent elements contributing their unique properties to the suture. He'll show that it's more likely than not that the coating on FiberWire does not materially affect the basic and novel properties.

When the evidence has all been presented, we believe you'll find that the idea for FiberWire was Mitek's

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idea and that a verdict finding in favor of Mitek is a fair and proper result.

We thank you. We look forward to presenting the evidence to you, and we thank you for your service. And before I close, I just want to introduce a few of the people you'll see in the courtroom so you'll know who the players are. You may have only seen the backs of their heads before. So my colleagues Mike Bonella and Lynn Malinoski are two of my partners at my law firm, and they'll be presenting witnesses for you. At the rear table on the right, you have Mr. Weber, who is the corporate representative for DePuy Mitek, and he'll be testifying. Next to him is Barbara McCormick. She's in-house counsel for Johnson & Johnson. And next to Barbara is Joe Ficocello. He's our technology specialist. And then we have three paralegals here who are hopefully keeping us operating smoothly, Jen Padinske, Marisa Browndorf, and Kate Wetzel. So you'll see them all scurrying around the courtroom.

Thank you very much for your attention.

THE COURT: Ms. Elderkin, do you want to take down the --

MS. ELDERKIN: Yes. Thank you.

THE COURT: Thank you. So we might go a little bit into the lunch period, but then I'll let you take a full hour for lunch before we come back.

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OPENING STATEMENT BY MR. SABER:

MR. SABER: I thought I was going to say good morning, ladies and gentlemen, but it's neither morning nor do we have any gentlemen, so I'll say good afternoon, members of the jury. I introduced myself earlier. My name is Charles Saber, and I'm an attorney representing the defendants here, Arthrex, Inc. and Pearsalls Limited. With me today is my colleague, Sal Tamburo. Sal's a lawyer at the same law firm that I am, and he'll be assisting in presenting the evidence to you.

Also seated at the counsel table is Mr. John Schmieding. John, can you stand up. John is the general counsel of Arthrex, and he is the corporate representative here today representing Arthrex and will be here for the trial. I'll tell you a little bit more about John in just a little bit.

Also here is Mr. Lawson Lyon. Mr. Lyon came here from England, and he's what's called the managing director of Pearsalls. That's a term we don't use here in the United States, but it's really equivalent to the CEO. As I said, Mr. Lyon as well as Mr. Schmieding will be here for the rest of the case.

Well, today in this opening statement, I'm like a tour guide on the first day of your vacation. I'll be giving you a tour through the evidence, providing a preview of what

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the witnesses will be saying and what the documents will show. Ms. Elderkin gave you her tour. I'll be giving you a little different tour, one that we believe is actually a little more accurate to the issues in this case.

First, let me tell you just a little bit about the parties, who we are. Arthrex is a Florida company located in Naples, Florida. You heard Judge Saris mention several people from Naples. They're Arthrex people. It's a relatively new company, beginning in 1982. It was started by a man named Reinhold Schmieding. That's John Schmieding's older brother. Reinhold Schmieding still runs the company today, and he asked his brother John to move to Florida a few years ago to help him supervise legal matters like this one. John like me is a lawyer. Arthrex, even though it's grown, it's still a family business.

Before Mr. Schmieding started Arthrex, he became fascinated with a new surgical procedure called arthroscopy. Now, this happened in the 1970s. It was very, very unique then, though today I think most of us are familiar with it. It's arthroscopic surgery. Ms. Elderkin told you a little bit about it. That's where a surgeon can make a very small incision in the skin, and using cameras and sophisticated instruments, he can perform complex procedures while minimizing the trauma that the patient is going to suffer.

And while arthroscopic surgery has many, many uses,

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I agree with what Ms. Elderkin said. Probably its most famous use, its best-known use is in the world of sports medicine, not just the athletes, though they do use it, but if you and I have a little problem, we maybe tear something or hurt something while jogging, we may go through arthroscopic surgery again.

Well, Mr. Schmieding, he decided to dedicate his career to advancing arthroscopy, and he started Arthrex in 1982. His first office was right up here in New England in Vermont, and he made the first instruments by hand by himself. It was ten years later the company was -- like a lot of small companies, just started up -- it was ten years later he hired his first engineer, Mr. Don Grafton, who Ms. Elderkin referenced to. And you're going to hear about him of course in this case. He doesn't work for Arthrex anymore, but he is one of the engineers who designed FiberWire, the product that we'll be here talking about today. Well, eventually Arthrex moved down to Florida, and they've grown over the years, and they're very proud of their growth. Now they have over 500 employees in the U.S., starting from just the few that they had up here in New England.

Well, Arthrex's mission is to help surgeons treat patients better and contribute to safe and successful patient outcomes. Arthrex accomplishes this mission by making

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meeting surgeons' needs their very top priority. How do they do this? They're constantly talking to the surgeons, constantly trying to find out what surgeons want. They're always working on developing new products and trying to improve their existing products. Also, they pride themselves as being a very, very nimble company. They're always trying to be the first one to market with new and improved products to meet their customer needs.

I tell you this because you're going to hear this. This is exactly the story of where FiberWire came from. They talked to the surgeons, they worked hard to develop a new product, and they were the first to market with a new high-strength suture.

Let me tell you a minute about Pearsalls. It's not a very big company, but it is a much older company. It was actually formed in England in 1795. It's a manufacturing company that specializes in braiding many materials together, with braided suture materials being its main business. It's the company that makes the braids for FiberWire. In fact, Pearsalls as a company has been in the business of making suture material for about a hundred years. It's located in Taunton, England. I expect that Taunton, Massachusetts, like so many cities and towns here in Massachusetts, is named for the English town. I know the one I grew up in was too.

I'd like to tell you that Mr. Lyon founded

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Pearsalls like Mr. Schmieding did for Arthrex, but of course that wouldn't be true. He wasn't around in 1795. He has, however, been with the company for almost thirty years, and he's heavily involved in all aspects of the corporation.

Now, as Ms. Elderkin told you, DePuy Mitek is a competitor of Arthrex. It's one of the many companies that comprise the Johnson & Johnson group of companies. It's a corporation, a large corporation, which last year had over $50 billion in sales.

Now, as Judge Saris told you, this is a patent infringement lawsuit. There are many, many issues in a patent suit. Sometimes you're fighting about the validity and sometimes enforceability. We're making it easy for you folks. We're only going to talk about one issue, the infringement issue. The other issues will be decided in another place at another time.

Now, Judge Saris told you a little bit about a patent. It's really just a bargain between the inventors and the public. In exchange for their ideas, the inventors get an exclusive right to exclude others for a period of time, and after that, the invention is dedicated to the public.

Inventors, however, they don't get protection for everything that's ever mentioned in the patent. Their protection comes from those claims that Judge Saris told you about. That's really what we mean when someone infringes a

patent. It's not about what the specification says. It's about what the claims say. The claims, they're like a deed to property. It defines what your property line is. If someone comes onto your property line, that's an infringement. If someone comes close to your property line or stays off your property line, even if they're competing with you, and even if they do other things that are said in the specification, they don't violate your rights because they're not practicing what's in the claims.

Now, this is very important because, you know, if a product is an infringement, then the public is going to be deprived of the right to buy that product, and there will be less competition. Now, if it's truly an infringement, I guess that's okay. That's what the system is for. But if it's not, if it's not an infringement, not only is the company or the person who's accused of infringing hurt, but so is the public, because the public is being deprived of a choice that they have every right to have.

Now, of course, DePuy Mitek is asserting the '446 patent in this case. You heard Ms. Elderkin say that it was Mitek that developed it first. That's not exactly right. As you'll see, actually, DePuy Mitek had nothing to do with the research that went into the '446 patent. That was done by Ethicon in the 1980s, long before DePuy Mitek was ever a part of the Johnson & Johnson companies. In fact, DePuy Mitek

only obtained the patent in 2004 just a few months before this lawsuit started.

Ms. Elderkin told you correctly, you won't hear that DePuy Mitek uses the '446 patent. They don't. They're not the only one who doesn't use the '446 patent. Ethicon didn't either. In fact there's no one on the Johnson & Johnson companies or anyone else who ever used the '446 patent.

Now, let me tell you a little bit about FiberWire, the suture product that's accused of infringement. Here it is. This is actually a sample of it. It comes in a sterilized package. They want to make it kind of hard so you can't mess it up. You know, the surgeons only use it once, just put it in the body, that's it. But ultimately here's the length of the suture of FiberWire, just so you can see what it is. I know when I was a kid we used to call them stitches. I guess they probably still do, but suture is technically what it is, and it can be done to just stitch up parts of the body. In fact, FiberWire is used for that, but it's also used in surgical situations too.

Now, the first thing that I'd like you to remember about FiberWire is that it has a silicon coding applied to it. And I listened to Ms. Elderkin, and she didn't get to the coating issue until the last five or ten minutes of her opening. I don't think they have a whole lot to say about

that, but we'll have a lot to say about the silicon coating.

When you look at the claims of the '446 patent, as Judge Saris gave to you, you won't see the word "coating" in there, and, again, everyone agrees on that. No dispute FiberWire has this silicon coating; no dispute it's not in the claims. But the question that we're going to ask you to decide is: Why is the coating on FiberWire, and what does it do? That's the issue that we're here to decide this week.

As you hear the evidence in this case and as you're deciding that question, I ask that you keep a couple of terms in mind. The most important term that I ask for you to keep in mind is "suture handleability." Well, what is that? It covers lots of things, but basically it's the ability of a surgeon to use a suture easily during surgery. In arthroscopic surgery like what this product is used for, the surgeon has little room to maneuver, and he must move quickly.

Now, you're going to hear about some suture properties like knot tie-down and run-down, and they refer to the ease by which the surgeon can slide a knot down the suture. I'm not very good at it, and I won't do it, but the surgeon ties knots outside of the body and has to slide them down the suture. That's called knot run-down, sometimes called knot tie-down.

As I say, these knots are made outside, and then in

arthroscopic surgery you have to slide them down to get them into the body. You have to do it quickly, you have to do it efficiently, and you have to do it without problems.

You'll also hear another handleability term called "tissue drag." Now, remember Ms. Elderkin told you that the suture actually goes through tissue. That's true in arthroscopic surgery as well. Well, you want to make sure that it goes through quickly and it goes through without tearing up the tissue any more than it has to. Those are really, really important issues, and we want to make sure that the suture which is going through that tissue does as little damage as possible.

Now, I'm going to talk a little bit more about that in just a few minutes, but I want you to keep one thing and I ask that you keep one thing in mind because the evidence will show something very, very simple: The FiberWire coating substantially improves suture handleability. In fact, it's critical to suture handleability. We will present you overwhelming evidence that the coating is critically important to knot run-down or knot tie-down, tissue drag, and the other aspects of suture handleability and pliability. And if after hearing the evidence you agree with me, then I will return at the end, and I'll ask you for a verdict of no infringement.

Now, Ms. Elderkin talked about the patent quite a

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bit, and she told you that the patent says that you can add a coating. The patent says lots of things, and I'm not going to take a lot of time with you right now, but this was a patent where they described the problems that coating brought in and said, "We have a solution where you don't have to use the coating." Remember she told you that you get all the benefits from the mechanical blending? Well, that's just not so for FiberWire. They have the coating. In fact, the patent says it's best not to use the coating. You can save the expense, you can save problems that coating brings in, because they think they can do it just with the mechanical blending. You can't with FiberWire.

We think that that issue of talking about these teachings of the patent, and it will be all over the place, really misses the point here. The real thing that we ask you to focus on is: Why is there coating on FiberWire, and what does it do? That's the issue for you, and that's the issue that we ask that you consider during this case.

Let's go back to our tour, if we can. Let me tell you a little bit about how FiberWire came about. You know, as I told you, Arthrex specializes in arthroscopic surgery, and it didn't sell sutures before FiberWire. But they're always talking to the surgeons. In the late 1990s, as these arthroscopic procedures were becoming more popular, they started hearing about how there was this breakage problem,

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how surgeons were pulling on the suture and there was breakage, not just on theirs but throughout the industry.

Now, Arthrex is a company that's always talking to their customers, always thinking about new ways to improve their products, always trying to get out first. So they knew about this breakage problem, and here's where Don Grafton and Lawson Lyon come into the story. Mr. Grafton was over in Taunton, England, visiting with Mr. Lyon. They actually worked together on a bunch of things. During that meeting over in Taunton, they discussed a material called ultra high molecular weight polyethylene.

Now, that's a mouthful, but it's one of the strongest and maybe the strongest synthetic material ever created. Pearsalls had been using that product, ultra high molecular weight polyethylene, for other products such as fishing line. Mr. Grafton and Mr. Lyon discussed using this material to use it for sutures. It was so strong it could solve the breakage problem. After some trials, it was decided to add the PET, a material that's very, very commonly used in sutures, and Arthrex thought they had a great idea; the suture would be very strong, and the knot would stay together.

Well, where does coating fit into the tour? That's really the issue that's involved in this case. This new suture, like many sutures in the market, are made by a

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braiding process. Well, there's nothing mysterious about braiding. It's just twisting two things together. You can braid your hair. Rope is braided. Many other things are braided. The same thing for a surgical suture. Not all of them are braided, but many of them are.

I don't think I have to tell you this, I think we all know this, that a braid just simply isn't that smooth. Just think of your hair when you braid it together. I know I've worked with my daughter's. It's kind of a rough surface. It's not a smooth surface. The same thing is true for a braided surgical suture. Now, it's a much finer braid than a rope or your hair, but it's still not smooth.

You've got to remember, these products are used in surgery where things have to be very precise. You know, in lots of situations in life, we use an analogy. We say that things have to be done with "surgical precision" when something has to be done precisely. But in this case, we're not talking about an analogy. We're talking about surgery. Surgeons must act with surgical precision.

Well, Mr. Grafton and Mr. Lyon, they immediately knew that it was absolutely necessary for the FiberWire suture to be coated. The coating smooths out the braid so that the suture slides smoothly when surgeons are tying knots and when the surgeons are pulling the knots down the suture and into place. Surgeons have to make those knots quickly,

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efficiently, and without the need for undue force.

The coating also smooths out the suture so it won't drag through the tissue in surgery. If the tissue is rough and it goes through, it can cause greater damage to that tissue. That is not a good thing. Mr. Grafton and Mr. Lyon knew that coating was absolutely necessary to meet those surgeon needs. Indeed, the new such, FiberWire, simply can't be sold without the coating.

Now, Pearsalls, the company that had been making suture material for a hundred years, they suggested the specific coating to put on FiberWire. They didn't suggest just any old coating. They suggested a silicon coating called New Silk 2174. This is a coating that Pearsalls had already been using. It is a coating that uses a manufacturing process that Pearsalls had perfected twenty years ago. It's a coating that Pearsalls has successfully used on millions of sutures over the years without complaint. It is the coating used on FiberWire. You'll hear Mr. Lawson this week explain all of this to you.

On this basis alone, I think you can see that the effect on suture handleability is dramatic, important, and necessary. But there's much more that we're going to tell you. We're going to show you statement after statement from the literature in the field that shows exactly why coating is added to braided surgical sutures. We'll show you witness

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after witness from Ethicon and DePuy Mitek themselves who agree that coating is used to improve suture handleability. There simply will be no doubt.

Well, these reasons are so well known in the field that companies don't routinely do tests to check coated and uncoated FiberWires. It's kind of like a car manufacturer trying to test to see whether you need a tire on a car. At some point you just kind of know that you've got to have a tire. Nonetheless, because this issue has been raised, we got some objective testing done that goes into some of the specific factors that go to suture slide, tissue drag, pliability, the things that I've talked about.

You'll hear first about some internal tests done in Arthrex when Johnson & Johnson first complained to Arthrex. That evidence will be presented by Arthrex's director of research and development, Ms. Ashley Willobee. You'll see on the test report her name is Ashley Holloway. She did the test in 2004, but she's married now, so she goes by her married name.

You'll also hear this kind of testing evidence from an outside expert, Dr. Norman Gitis. He's the director of the Center for Tribology. Dr. Gitis and his company are well-known experts in suture testing. Most of the major suture companies, including Ethicon, DePuy Mitek's sister company, have hired Dr. Gitis and his company to do suture

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testing. He'll explain the various tests that he did which confirm everything that I've just told you about how FiberWire's coating affects suture handleability and pliability.

You'll also here from orthopedic surgeons. Ms. Elderkin told you about one of them, but I'll tell you about the other one, Dr. Stephen Burkhart. He was actually involved in the development of FiberWire. He wasn't the major person. He's not a person who was the one who came up with the idea, but he's a consultant to Arthrex, and he was asked for his comments as it was being developed. And he'll come in here, and he's going to tell you, yeah, he thought it was a great idea, just like Ms. Elderkin said. But he also said he knew it had to be coated. He talked to Mr. Grafton about it. He said, "You know, you can't do this without coating it. You've got to do it. I'm a surgeon. Believe me, this has to be a coated suture."

And you'll also hear from Dr. Burks. It's right he said some of the differences were not the biggest differences in the world, but, you know, he did the blind tests for his report. They tried to trick him at his deposition. He did the blind test again. He got it right every time.

Now, finally, you're going to hear the testimony of Dr. Debi Mukherjee, a renowned suture expert, who will explain to you from a highly qualified expert's point of view

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exactly why coating is added to surgical sutures and why the evidence in this case overwhelmingly establishes that the FiberWire coating is important to handleability and pliability.

Let me tell you a little bit about Dr. Mukherjee. He's sitting over there now. He's actually the only one back there that's from our side. He's in his late sixties. He came to this country from India as a struggling student about forty years ago. He got his doctorate degree down the street at MIT, and he stayed in this country and built a successful career studying, developing, manufacturing, and teaching about surgical sutures. Today he's a medical school professor. He teaches medical students and doctors about medical materials they put into the body, including surgical sutures. He's the one who teaches the doctors how sutures react in the body, how they're made, and about their properties.

But he's done much more with sutures than just teach it. He's written chapters in books and various articles about sutures, and he spent thirteen years of his professional career working for a leading suture company in Connecticut called Davis and Geck. During those thirteen years, Dr. Mukherjee worked with sutures almost every day, developing them, manufacturing them, testing them. He was heavily involved in the coating of sutures. He supervised

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the coating operations at Davis and Geck for part of his time there. It's hard to conceive of a more qualified expert.

Well, what is DePuy Mitek going to have to say? When it gets to the coating, I suspect very little. They will not present evidence that these universally known reasons for coating sutures is wrong, and they won't give you any objective testing evidence. I expect they'll try and cut up some of our experts. They'll try and tell you that their tests are unreliable. They may even give you the testimony -- I think they will -- from Dr. Brookstein, their suture expert.

Well, like Dr. Mukherjee, Dr. Brookstein is a professor; but unlike Dr. Mukherjee, Dr. Brookstein has very little experience with sutures, and he has no prior experience working with suture coatings. Really his expertise is textile braiding, and that he can probably tell you about. But when it comes to the coatings, he's not the guy, and I ask you to keep this difference in mind as you're deciding the issues in the case.

Well, let me now get to the final leg of the tour. We're almost home. After finishing the development of FiberWire and obtaining the necessary governmental approvals, Arthrex introduced FiberWire into the marketplace in August of 2001. It was the first high-strength suture to hit the market, and one thing we agree on: It's been a success.

Arthrex does believe that it's played a role in revolutionizing arthroscopic surgery because FiberWire is so much stronger than conventional sutures that were previously made in the market. But, as we've discussed, just having a strong suture isn't enough. It's got to provide the other things a surgeon needs, like the good handleability, including the ability to tie down knots and all the things we talked about. Arthrex's marketing literature says it meets these needs. It doesn't say, "We coat to meet these needs." It doesn't have to. Everyone knows that. But their directions for use do, and it says that we added the coating, the silicon coating, to improve knot suture slide, tying characteristics, and to lower tissue drag. Mr. Bill Benavitz, the marketing manager who's in charge of marketing products that have FiberWire, will tell you all about this.

Well, how did the marketplace react to this new product, this first high-strength suture to hit the market? Well, like most successful new products, the competitors one by one introduced their own versions of high-strength suture.

Well, what about DePuy Mitek? They're not quite the same kind of company as Arthrex. Frankly, they were a little asleep at the switch. In fact, they were the last significant competitor to introduce a high-strength suture. They call it Orthocord, and as I told you, you won't hear

that they use the '446 patent for Orthocord. You will hear maybe a little bit that they use coating on Orthocord, and you'll hear the same reasons that they use coating on Orthocord, a braided suture, is the same reasons that it's on FiberWire.

Well, ladies and gentlemen, I know it's getting right near the lunch hour. I'm happy to tell you I'm right at the end of the tour for the evidence. As I mentioned earlier, we believe that the evidence overwhelmingly will show that FiberWire coating has a substantial and important effect on suture handleability and pliability. If you agree with that, as I hope and expect that you will after you hear the evidence, I will be back to address you again at the end of the case and ask you to return a verdict of no infringement.

Thank you very much for your patience, and I hope you all enjoy your lunch.

THE COURT: Great. I'll see you in an hour. I did want to mention one thing, which is downstairs we have an excellent lunchroom that you're welcome to use. You're also welcome to go outside. There are some great tables in the corner that overlook the ocean and that sort of thing. But if you see any of the people involved in this trial, my clear instruction to you is be rude.

(Laughter.)

THE COURT: You can't talk to them, you can't discuss the weather, because as soon as you do, you know, the other side sees and they think that someone's hobnobbing with the jury, and I end up having an embarrassing little hearing about what was discussed. So, please, they understand the rules of the game. They don't really think you're being rude. So if you happen to be behind them in line or bump into them or wherever, just keep on going. Anyway, have a great lunch break.

THE CLERK: All rise for the jury.

(Jury excused, 1:15 p.m.)

THE COURT: We should gather around 2:15. And just because I know Ms. Marzilli is trying to figure out what to do this afternoon, how long do you think the testimony will be of your witness?

MS. ELDERKIN: Less than a half an hour for Mr. Weber.

THE COURT: And on the cross?

MR. SABER: Twenty minutes to a half an hour.

THE COURT: So let's say 2:15, 3:15. Then we'll go into the deposition, where we all agree that that does not need to be transcribed.

(Discussion off the record.)

(Noon recess.)

AFTERNOON SESSION

THE CLERK: All rise. Please be seated.

All rise for the jury. Please be seated.

THE COURT: Your first witness.

MS. MALINOSKI: Depuy Mitek calls Mr. Neil Weber.

NEIL WEBER, having been duly sworn by the Clerk, testified as follows:

THE CLERK: You may be seated, and would you please state your name and spell it for the record.

THE WITNESS: Hi, my name is Neil Weber, N-e-i-l W-e-b-e-r.

DIRECT EXAMINATION

BY MS. MALINOSKI:

Q. Good afternoon, Mr. Weber. Would you please introduce yourself to the jury.

A. Yes, again my name is Neil Weber. I'm vice-president of marketing for Depuy Mitek.

Q. Where is Depuy Mitek located?

A. Depuy Mitek is located in Raynham, Massachusetts.

Q. Would you tell the jury a little bit about your educational background after high school.

A. Yes, I graduated from Princeton University with a criminal engineering degree in 1994, and I also have a master's in business from Harvard University which I earned in 1999.

EXHIBIT 18

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DB000172

DEPUY MITEK
EXHIBIT 553
04cv12457

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EXHIBIT 19

				Dye							Intermediate							Measure						
				Knot			Straight				Knot			Straight				Knot			Straight			
Bates	Batch	Product	Size	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter
PR 4095	28261	Blue PE Med2174	050	15.68	13.40	18.00	33.10	29.00	36.60	574	17.10	16.60	17.60	35.90	33.90	38.60	580	15.61	14.50	17.40	36.62	33.20	38.40	596
PR 3592	28260	Blue PE Med2174	050	15.53	14.30	16.50	35.09	31.40	38.00	589	16.10	15.20	16.80	35.78	32.80	39.60	586	16.37	15.00	18.00	36.82	33.50	40.30	594
PR 3600	28259	Blue PE Med2174	050	15.28	14.10	16.20	36.28	33.00	38.30	583	16.00	15.80	16.20	38.01	35.80	39.90	575	15.77	14.50	17.10	36.56	31.90	40.50	582
PR 3608	28258	Blue PE Med2174	050	15.74	14.70	16.30	37.03	35.30	40.00	602	15.47	13.60	16.90	34.06	31.30	39.60	611	18.01	16.00	19.20	38.31	32.80	40.40	593
PR 3616	28257	Blue PE Med2174	050	16.44	15.20	18.10	35.28	32.50	37.20	596	16.50	15.30	16.30	35.51	30.90	39.80	594	16.29	15.00	18.10	34.39	31.70	37.20	590
PR 3624	28256	Blue PE Med2174	050	15.86	15.00	17.00	35.12	33.30	40.30	580	15.60	14.70	16.60	34.69	29.60	38.00	589	17.35	15.40	19.20	36.71	33.10	38.60	583
PR 3633	28255	Blue PE Med2174	050	15.14	14.40	16.00	33.60	30.40	38.10	583	15.47	15.30	15.60	38.32	32.40	40.50	606	15.83	14.70	17.70	35.58	31.00	40.90	608
PR 3641	28254	Blue PE Med2174	050	14.92	14.00	16.30	36.27	33.30	38.10	604	15.40	14.50	16.50	35.57	30.80	37.60	600	16.43	14.30	19.10	35.24	32.80	38.70	575
PR 3649	28253	Blue PE Med2174	050	14.81	14.10	15.60	34.16	31.80	38.70	587	15.77	14.80	16.80	35.40	33.60	36.70	582	15.39	14.70	16.60	35.48	32.20	37.70	574
PR 3657	28874	Blue PE Med2174	050	16.34	14.60	18.40	35.99	34.10	39.20	591	15.73	14.70	16.40	35.76	29.80	39.70	591	15.55	14.21	16.90	34.85	32.90	36.50	578
PR 3672	28873	Blue PE Med2174	050	15.89	14.10	18.00	35.46	30.60	38.70	592	14.80	14.70	14.90	32.29	30.90	34.70	603	15.70	14.30	17.50	34.64	31.50	37.30	615
PR 3680	28872	Blue PE Med2174	050	16.61	14.40	18.60	34.97	32.80	38.20	590	14.93	14.40	15.30	34.58	29.40	37.60	607	15.05	13.30	17.20	34.31	29.40	37.60	597
PR 3688	28870	Blue PE Med2174	050	15.21	14.20	15.70	34.30	30.40	39.50	575	15.83	14.80	17.00	36.50	33.80	39.70	609	15.76	13.20	17.30	35.01	32.80	37.20	590
PR 3696	28869	Blue PE Med2174	050	16.30	14.50	18.10	35.92	31.90	39.60	587	15.80	13.90	17.50	34.52	31.70	38.70	610	16.29	14.20	17.70	33.27	30.30	38.30	606
PR 3704	28868	Blue PE Med2174	050	15.92	14.80	17.00	38.14	34.10	40.50	561	16.63	16.20	17.10	36.36	33.00	39.30	590	15.83	14.20	17.30	34.69	31.70	38.30	572
PR 3712	28867	Blue PE Med2174	050	16.16	14.80	17.30	36.87	34.10	40.50	605	16.43	15.00	18.20	36.82	33.90	39.20	581	17.49	15.80	18.80	35.91	32.90	40.10	561
PR 3720	28866	Blue PE Med2174	050	15.64	14.70	17.20	35.96	31.50	38.00	570	16.90	14.60	19.00	35.62	32.50	39.50	578	15.53	13.30	18.00	36.28	33.30	40.60	568
PR 3735	28865	Blue PE Med2174	050	15.69	14.60	16.70	35.32	30.30	39.80	563	14.93	14.50	15.70	31.63	30.10	35.00	571	16.75	15.40	18.70	32.77	30.50	37.20	577
PR 3749	28864	Blue PE Med2174	050	15.78	14.40	17.90	35.00	32.90	38.10	553	16.18	15.20	17.40	35.69	31.50	38.70	564	14.92	13.60	16.50	33.69	30.80	37.40	587
PR 3763	28863	Blue PE Med2174	050	15.22	13.50	16.50	33.27	31.50	35.50	575	16.87	15.80	17.60	35.80	32.10	38.70	599	16.52	15.10	18.60	36.28	34.00	38.60	581
PR 3776	25899	Blue PE Med2174	050	15.61	14.60	17.50	33.71	30.50	35.50	558	14.83	13.90	15.90	33.76	30.70	35.80	565	16.62	14.70	18.30	35.54	33.30	37.70	593
PR 3792	25896	Blue PE Med2174	050	16.27	15.10	18.10	35.44	32.30	39.30	566	15.40	14.00	16.40	36.26	33.30	38.20	572	15.50	14.00	17.40	35.49	32.40	37.40	589
PR 3808	25897	Blue PE Med2174	050	15.84	14.50	16.90	35.13	32.20	39.60	547	16.23	15.20	17.10	35.96	33.20	38.70	597	15.79	14.60	17.00	35.53	32.50	37.70	577
PR 3822	25896	Blue PE Med2174	050	16.60	15.20	18.70	35.62	32.90	38.70	590	17.13	16.20	18.50	35.57	31.10	38.90	552	16.72	15.40	23.00	35.26	30.70	39.70	583
PR 4668	25895	Blue PE Med2174	050	16.13	14.80	18.60	36.20	34.40	38.30	585	18.20	14.70	19.10	34.41	31.50	36.90	596	15.09	13.70	17.00	31.87	28.70	33.80	568
PR 4337	25893	Blue PE Med2174	050	14.89	13.50	17.70	32.32	29.80	35.20	557	17.73	16.90	18.60	35.87	34.50	37.20	585	17.27	15.60	19.20	33.01	31.30	35.00	550
PR 4351	25892	Blue PE Med2174	050	16.33	15.00	17.70	33.83	29.30	36.20	577	16.30	15.30	17.60	37.61	36.90	39.10	583	15.57	14.70	16.70	33.22	30.20	35.80	558
PR 4366	25891	Blue PE Med2174	050	14.84	14.20	15.80	35.52	33.90	36.90	575	15.63	14.90	16.60	35.17	32.20	37.00	562	16.49	15.20	17.60	35.13	32.70	39.20	576
PR 4380	25890	Blue PE Med2174	050	14.59	13.30	17.20	33.31	29.70	39.70	562	15.53	15.10	15.90	34.24	30.90	38.10	562	15.68	14.60	17.50	36.20	31.90	39.80	574
PR 4396	25889	Blue PE Med2174	050	14.69	13.60	15.30	35.68	33.70	38.10	562	16.03	15.50	16.40	35.62	33.40	37.70	564	17.56	15.60	20.20	36.27	33.70	38.90	579
PR 4410	25888	Blue PE Med2174	050	15.48	14.70	16.30	35.09	31.60	38.70	577	15.33	15.10	15.70	34.13	31.50	36.80	580	15.22	14.30	18.10	32.96	31.90	35.90	561
PR 4424	25887	Blue PE Med2174	050	15.12	12.80	16.90	34.57	30.90	38.70	558	17.80	16.60	19.40	35.86	28.90	38.00	574	15.31	14.50	16.40	37.57	34.00	40.90	565
PR 4439	25886	Blue PE Med2174	050	16.27	13.00	18.60	34.18	31.30	37.20	582	16.40	14.70	19.00	35.42	33.30	36.80	561	16.91	15.20	20.10	34.96	30.90	37.80	573
PR 4653	25885	Blue PE Med2174	050	15.63	13.70	16.20	35.00	32.20	37.30	576	15.27	13.90	16.50	36.30	33.80	39.60	552	15.22	14.40	16.70	34.38	31.20	37.20	566
PR 4454	25884	Blue PE Med2174	050	15.48	14.50	17.30	36.01	32.30	39.70	559	16.63	15.40	17.30	35.19	30.70	38.20	556	15.61	14.60	17.70	34.40	31.90	38.60	558
PR 4469	25883	Blue PE Med2174	050	14.82	13.20	16.60	34.18	31.90	38.50	582	15.60	14.90	16.40	35.99	32.30	38.80	568	15.76	14.20	18.10	33.99	32.10	36.70	572
PR 4484	25883	Blue PE Med2174	050	14.82	13.20	16.60	34.18	31.90	38.50	582	15.60	14.90	16.40	35.99	32.30	38.38	568	15.76	14.20	18.10	33.99	32.10	36.70	572
PR 4499	25882	Blue PE Med2174	050	15.03	13.70	17.00	33.18	29.30	37.80	589	16.03	15.00	17.60	36.73	33.00	40.20	574	15.03	14.30	16.00	35.13	32.20	37.20	580
PR 4103	25881	Blue PE Med2174	050	14.93	14.40	15.60	33.74	28.90	37.60	574	16.07	15.10	17.70	35.46	32.80	38.20	557	15.56	14.40	17.40	35.06	32.80	36.80	574
PR 4118	25880	Blue PE Med2174	050	15.19	14.60	15.70	34.91	32.10	39.50	591	15.77	15.30	16.30	36.27	30.30	38.80	558	16.19	14.80	18.40	34.64	33.40	37.60	572
PR 4132	25879	Blue PE Med2174	050	14.47	13.60	16.70	35.52	33.30	39.00	580	15.60	15.00	16.10	34.13	31.40	37.50	567	15.43	14.00	16.90	35.76	32.40	38.00	560
PR 4148	25878	Blue PE Med2174	050	15.53	14.20	16.50	35.31	31.30	37.90	586	14.97	14.20	15.50	34.23	32.70	36.30	564	16.03	14.70	19.30	32.82	29.50	34.10	554
PR 4162	25877	Blue PE Med2174	050	14.89	13.20	17.90	32.09	27.80	40.90	550	15.13	14.40	16.40	34.69	32.10	37.50	560	15.47	14.70	17.00	35.87	32.90	39.60	573
PR 4176	25876	Blue PE Med2174	050	16.16	14.70	17.70	34.20	32.00	37.10	573	16.17	15.60	16.80	36.87	33.20	40.30	550	16.13	14.70	17.30	34.89	32.00	37.60	561
PR 4191	25338	Blue PE Med2174	050	15.07	14.20	16.90	35.29	31.80	38.70	585	16.43	15.70	16.90	35.73	32.70	37.90	570	16.35	14.70	20.50	35.43	33.40	38.10	582
PR 4208	25337	Blue PE Med2174	050	14.93	14.30	15.70	33.62	30.90	37.00	579	16.10	15.30	16.90	33.98	30.60	37.40	556	15.55	14.00	17.90	33.02	30.30	35.10	555
PR 4220	25336	Blue PE Med2174	050	15.64	14.70	17.20	35.62	32.80	38.20	586	15.73	15.10	16.50	36.98	34.50	39.60	551	15.91	14.60	18.70	33.67	31.00	35.80	572
PR 4235	25335	Blue PE Med2174	050	15.34	14.50	16.10	33.79	29.00	37.40	585	15.97	15.20	16.80	37.53	34.20	40.10	565	17.15	14.90	18.80	36.06	29.50	40.20	561
PR 4250	25334	Blue PE Med2174	050	15.51	14.10	17.70	33.59	29.80	36.90	589	17.33	16.50	17.90	33.71	30.90	36.60	556	16.38	14.70	18.00	36.52	32.80	39.20	580
PR 4264	25333	Blue PE Med2174	050	14.42	13.70	15.30	33.43	27.80	37.40	590	16.57	15.60	17.40	34.58	31.80	37.50	567	15.67	14.60	17.30	37.13	34.10	39.70	567
PR 4279	25332	Blue PE Med2174	050	16.22	14.70	18.10	36.89	33.00	40.10	566	16.13	15.30	16.80	33.44	30.10	37.30	576	16.90	15.10	19.70	34.52	30.70	37.10	562
PR 4294	25331	Blue PE Med2174	050	15.81	14.60	17.90	35.69	34.00	37.50	565	16.67	16.10	17.10	34.84	31.20	37.60	548	17.13	15.50	19.90	34.81	32.70	38.10	571
PR 4308	25330	Blue PE Med2174	050	16.26	13.70	17.00	33.37	31.60	37.70	565	16.53	16.00	17.30	36.07	30.90	38.30	566	16.75	15.20	18.30	34.36	30.30	36.90	562
PR 4322	25329	Blue PE Med2174	050	15.52	14.70	17.20	34.42	30.90	36.80	566	16.00	15.40	16.80	34.28	29.80	38.10	547	16.02	14.70	17.60	34.58	31.70	37.10	564
PR 3638	25328	Blue PE Med2174	050	15.39	14.40	16.10	36.59	32.10	40.90	571	17.33	16.90	18.20	37.48	33.50	39.20	560	16.24	14.90	17.60	35.44	33.80	36.70	561
PR 3653	25327	Blue PE Med2174	050	16.48	15.00	17.60	30.23	26.50	34.20	562	17.03	16.50	17.70	34.69	30.90	37.70	558	16.83	15.60	18.10	36.52	31.90	38.70	582
PR 3667	25326	Blue PE Med2174	050	15.56	13.80	16.70	33.74	30.50	36.60	571	16.83	15.40	17.90	36.09	35.10	38.90	577	16.57	15.00	17.80	35.24	32.00	37.70	559
PR 3681	25325	Blue PE Med2174	050	15.86	14.40	17.10	34.61	29.90	37.70	571	16.10	15.10	17.80	34.41	31.00	37.80	561	15.35	14.80	16.30	36.49	31.80	40.40	560
PR 3696	25324	Blue PE Med2174	050	15.03	13.70	16.00	34.91	32.50	37.50	589	15.27	14.80	15.80	34.80	31.40	36.00	557	16.31	14.90	18.10	35.62	32.80	40.30	555
PR 3906	25323	Blue PE Med2174	050	15.39	14.20	16.70	32.69	25.80	38.70	585	16.27	15.70	17.20	35.00	33.90	36.80	557	16.33	15.10	17.40	34.36	32.70	36.90	561
PR 3922	25322	Blue PE Med2174	050	15.72	14.50	17.10	34.03	31.40	38.50	570	15.90	14.80	16.50	36.98	33.10	38.20	573	16.38	15.20	17.20	35.90	33.10	38.60	577
PR 3936	25321	Blue PE Med2174	050	16.26	14.90	17.10	36.57	30.20	38.90	579	16.37	15.30	17.60	36.21	34.40	38.70	561	17.50	16.00	20.10	35.46	32.00	38.60	576
PR 3950	25320	Blue PE Med2174	050	16.70	15.60	18.60	36.09	32.20	40.30	576	15.60	14.20	18.20	33.42	29.90	38.70	570	15.75	14.60	17.40	35.38	30.60	38.70	575
PR 3965	25319	Blue PE Med2174	050	14.12	13.20	15.70	30.94	27.90	34.00	594	16.17	15.10	17.30	35.97	32.60	39.20	564	15.34	14.60	16.50	36.17	31.70	39.50	572
PR 3978	25072	Blue PE Med2174	050	13.53	12.10	14.70	31.37	27.40	34.00	576	14.73	14.10	15.30	32.19	29.10	37.30	578	15.65	13.90	18.30	32.17	27.90	34.60	570
PR 3993	24331	Blue PE Med2174	050	16.02	14.70	17.70	33.89	31.20	36.60	570	16.60	15.70	17.60	36.56	34.60	39.60	588	17.44	16.00	19.10	36.94	34.30	38.70	572
PR 4007	24330	Blue PE Med2174	050	14.77	13.20	16.90	34.48	30.30	40.00	595	16.58	15.10	17.80	34.17	30.80	37.30	559	15.69	14.60	17.90	35.97	31.00	38.10	565

Bates	Batch	Product	Size	Dye							Intermediate							Measure						
				Knot			Straight				Knot			Straight				Knot			Straight			
				Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter
PR 4022	24329	Blue PE Med2174	050	15.42	14.00	16.60	35.37	32.40	38.70	595	15.07	14.60	15.60	35.50	30.30	39.60	570	15.76	14.50	16.70	34.06	29.90	39.80	568
PR 4038	24328	Blue PE Med2174	050	15.01	14.20	16.00	35.36	31.60	37.70	601	14.80	14.40	15.10	34.99	33.20	38.40	570	16.09	14.40	17.60	34.88	32 30	36.90	567
PR 4067	24326	Blue PE Med2174	050	15.00	14.10	17.20	36.63	34.10	39.00	589	18.33	15.50	21.70	32.88	28.90	34.80	573	15.63	14.00	18.60	34.36	30.30	36.70	582
PR 4081	24325	Blue PE Med2174	050	14.99	14.00	16.20	34.68	32.90	37.40	588	14.87	14.50	15.10	31.61	29.60	33.40	579	13.93	12.40	16.00	31.18	29.10	33.40	564
PR 5516	24324	Blue PE Med2174	050	15.09	13.10	18.00	33.56	29.40	36.20	596	15.13	14.50	16.20	31.34	26.00	37.80	583	16.27	14.50	21.10	32.72	29.30	36 90	570
PR 5529	24323	Blue PE Med2174	050	15.39	14.70	16.30	34.32	30.20	37.10	589	15.77	14.20	16.60	33.17	29.60	36.70	588	15.96	14.90	18.00	32.63	29.20	37.00	565
PR 5544	24322	Blue PE Med2174	050	15.07	14.00	17.20	33.40	29.50	36.30	589	13.90	13.10	14.80	33.14	30.40	38.90	581	15.72	14.40	17.00	34.98	32.70	39 00	589
PR 5558	24321	Blue PE Med2174	050	14.59	13.30	15.70	35.06	26.30	40.20	590	15.93	15.00	16.90	33.73	31.40	36.60	579	13.81	12.70	15.50	33.77	31.90	35.20	591
PR 5572	24320	Blue PE Med2174	050	14.93	13.40	17.00	34.50	33.00	35.90	580	16.10	14.30	17.90	34.43	31.40	38.00	590	15.99	14.00	17.50	34.08	30.00	38.10	569
PR 5586	24319	Blue PE Med2174	050	13.63	12.50	14.50	31.87	30.00	34.80	584	15.43	14.20	16.50	30.98	28.70	33.20	561	14.53	12.40	15.90	32.06	28.80	34.20	561
PR 5600	24318	Blue PE Med2174	050	14.50	13.60	16.00	34.78	32.70	37.80	588	15.93	15.30	17.00	32.87	27.70	36.70	567	15.97	14.00	18.70	32.13	28.70	34.40	569
PR 5613	24317	Blue PE Med2174	050	14.59	13.30	16.30	31.03	26.60	34.50	581	15.70	15.10	16.10	31.51	28.80	35.60	584	15.19	14.40	16.80	30.51	26.20	34.50	582
PR 5626	24316	Blue PE Med2174	050	14.41	12.10	17.00	28.11	24.40	32.70	573	14.90	13.70	15.80	28.73	23.30	30.40	549	14.36	13.00	15.70	27.47	25.20	32.40	576
PR 5656	24314	Blue PE Med2174	050	14.39	13.50	15.30	32.17	27.90	35.40	580	13.70	13.00	14.50	30.06	27.70	33.00	571	15.82	13.70	19.50	32.06	27.30	35.60	574
PR 5672	24313	Blue PE Med2174	050	14.93	13.10	17.20	31.93	26.90	35.30	586	12.60	12.20	13.30	28.62	27.00	30.00	561	10.35	7.70	13.20	25.43	22.60	29.60	577
PR 5686	24312	Blue PE Med2174	050	14.02	13.00	16.30	30.23	26.10	35.00	575	17.77	16.60	18.70	32.14	28.40	35.80	583	15.48	13.70	19.00	29.04	26.20	30.70	562
PR 5700	24311	Blue PE Med2174	050	14.56	13.20	16.30	33.17	30.70	35.40	586	14.43	13.60	15.00	28.78	22.40	32.60	562	14.19	13.10	15.90	28.80	27.10	31.50	579
PR 5716	24310	Blue PE Med2174	050	13.86	12.90	14.40	30.86	26.90	35.10	586	13.40	13.20	13.60	31.06	28.60	33.60	588	14.65	13.10	17.00	31.50	28.70	33.40	573
PR 5731	24309	Blue PE Med2174	050	14.20	12.30	16.80	31.83	28.80	34.70	590	14.93	13.50	17.70	31.14	29.50	33.90	574	15.06	13.50	16.70	33.08	30.50	35.70	569
PR 5746	24307	Blue PE Med2174	050	14.60	13.90	17.00	33.49	31.00	36.10	591	14.30	13.50	14.70	31.50	29.50	32.70	591	13.75	12.90	15.80	28.56	24.20	31.20	567
PR 5760	23969	Blue PE Med2174	050	15.08	13.40	16.90	32.17	27.40	36.40	564	14.93	13.80	15.90	29.96	27.10	31.80	575	14.72	13.70	16.90	30.02	26.80	35.10	578
PR 5775	23968	Blue PE Med2174	050	15.26	13.40	16.50	34.39	31.60	35.90	583	15.50	14.80	16.00	33.42	28.90	37.40	587	14.79	13.00	16.50	30.54	28.20	33.10	565
PR 5791	23967	Blue PE Med2174	050	15.66	13.10	19.10	31.51	27.80	36.30	576	15.87	14.50	18.00	33.80	29.00	37.30	578	15.39	13.70	17.90	33.68	29.90	38.30	589
PR 5806	23966	Blue PE Med2174	050	14.20	12.80	16.60	30.43	27.80	32.60	569	16.70	13.50	19.10	32.46	26.90	35.30	569	14.15	13.30	16.00	28.81	26.80	32.40	573
PR 5822	23965	Blue PE Med2174	050	15.68	14.40	16.10	33.52	30.40	35.90	588	14.63	13.70	16.10	29.13	25.60	32.40	589	14.07	13.30	15.20	29.76	27.40	32.20	571
PR 5837	23964	Blue PE Med2174	050	15.76	14.30	17.20	32.28	28.10	37.80	583	14.17	13.20	16.10	29.87	26.70	34.30	586	14.28	13.30	16.30	29.52	26.60	32.60	573
PR 1	22178	Blue PE Med2174	050	14.52	13.60	15.30	32.30	28.80	35.20	579	15.67	14.00	17.30	30.93	24.50	34.00	575	16.93	14.60	19.90	33.01	29.50	35.80	567
PR 5853	20872	Blue PE Med2174	050	14.11	12.90	15.20	31.76	27.50	34.30	585	16.30	16.00	16.70	31.71	28.30	37.60	572	15.28	14.00	17.10	32.70	31.40	34.10	583
PR 5868	20871	Blue PE Med2174	050	13.64	12.40	15.70	30.41	29.10	32.10	600	15.80	15.10	16.40	29.18	25.20	32.00	583	14.46	13.40	15.90	31.16	25.90	35.30	574
PR 5884	20870	Blue PE Med2174	050	13.52	13.10	13.90	29.94	27.60	34.90	588	13.23	11.50	15.30	27.50	21.80	34.60	582	13.45	12.20	15.40	30.22	27.10	33.50	578
PR 5899	20869	Blue PE Med2174	050	13.91	13.20	15.10	31.60	27.50	36.30	590	14.93	14.50	15.30	30.57	27.20	32.80	564	14.57	12.30	16.70	31.76	30.30	32.80	562
PR 5913	20868	Blue PE Med2174	050	13.99	12.90	15.40	29.64	24.90	33.70	587	13.10	12.70	13.30	30.66	29.00	32.80	578	13.39	12.30	14.40	30.69	29.40	31.40	568
PR 5929	20867	Blue PE Med2174	050	14.56	13.30	15.60	31.67	29.30	35.20	586	13.50	13.10	13.80	30.26	27.70	32.30	570	14.66	13.00	16.20	31.17	27.40	32.60	583
PR 5944	20866	Blue PE Med2174	050	14.38	13.80	15.00	30.03	26.50	33.20	584	13.07	12.80	13.50	30.86	29.60	32.70	574	14.01	13.10	15.40	30.70	29.90	32.00	573
PR 5958	20864	Blue PE Med2174	050	13.54	12.30	14.20	32.17	29.50	34.80	593	14.50	13.50	16.10	30.38	28.60	32.10	565	13.97	12.40	15.70	29.61	27.80	34.30	564
PR 5974	20863	Blue PE Med2174	050	13.64	12.80	14.70	31.40	29.70	33.40	596	13.50	11.20	16.80	27.78	24.80	31.30	588	12.87	10.20	14.70	29.41	27.00	31.20	585
PR 5989	20862	Blue PE Med2174	050	13.63	12.70	14.50	31.11	27.80	35.40	588	16.07	15.70	16.50	31.51	29.00	33.10	574	14.34	13.30	15.70	33.29	31.80	36.40	580
PR 6004	20861	Blue PE Med2174	050	14.06	12.50	14.70	31.42	29.40	35.30	595	14.70	13.70	16.20	30.62	29.30	33.20	574	13.83	13.10	14.70	30.59	29.40	32.70	572
PR 6019	20860	Blue PE Med2174	050	14.17	12.30	16.50	30.80	27.90	33.70	590	14.50	13.30	16.00	32.76	30.70	33.80	581	14.46	13.30	16.50	32.21	30.40	34.30	580
PR 6033	20859	Blue PE Med2174	050	14.11	12.80	15.70	30.99	29.20	34.20	597	14.77	14.10	15.70	32.72	30.60	37.50	581	14.71	13.70	16.10	31.51	30.30	34.70	579
PR 6048	20858	Blue PE Med2174	050	14.39	13.00	15.30	32.28	30.10	36.00	586	15.27	13.40	16.50	31.69	28.60	33.80	578	14.53	13.00	17.20	31.88	30.00	34.20	579
PR 6063	20857	Blue PE Med2174	050	13.77	12.80	16.30	30.88	27.70	33.80	590	14.07	13.70	14.50	31.64	30.10	33.30	584	13.53	13.00	14.10	32.66	31.70	33.40	583
PR 6078	20856	Blue PE Med2174	050	14.50	13.20	16.50	31.98	30.10	38.40	594	15.20	13.70	17.10	32.91	30.60	35.30	584	13.89	12.50	15.10	31.63	30.20	33.50	579
PR 6093	20855	Blue PE Med2174	050	14.04	13.30	16.10	32.02	29.70	35.40	591	14.43	14.20	14.60	31.34	29.70	33.30	588	14.02	13.20	14.80	31.24	30.20	32.40	573
PR 6108	20854	Blue PE Med2174	050	14.09	13.30	15.20	33.09	30.10	37.10	604	15.17	14.10	16.20	31.67	29.70	33.20	587	14.18	13.30	14.80	32.04	30.60	33.90	578
PR 6124	19317	Blue PE Med2174	050	13.63	12.40	14.90	32.58	30.70	34.80	611	14.80	14.10	15.20	34.10	32.00	36.50	589	14.90	13.70	16.40	31.58	30.60	32.70	576
PR 6140	19310	Blue PE Med2174	050	14.92	13.70	16.70	32.59	30.70	34.10	597	14.83	14.40	15.10	33.74	30.40	38.10	591	15.25	13.10	16.60	31.22	30.10	34.10	591
PR 6158	19309	Blue PE Med2174	050	14.76	13.70	16.60	32.68	29.80	35.10	590	14.43	13.80	15.30	32.60	30.00	33.80	588	14.22	13.10	15.70	31.09	27.50	33.60	573
PR 6171	19306	Blue PE Med2174	050	14.60	13.70	16.00	32.62	27.80	36.70	579	16.00	15.30	16.40	32.48	30.20	35.80	584	14.79	12.20	17.10	31.69	28.40	34.50	573
PR 1711	19307	Blue PE Med2174	050	14.11	13.40	14.80	31.11	27.90	34.50	585	14.20	13.30	15.30	31.73	30.20	35.60	581	14.84	13.90	16.70	31.49	29.30	33.40	581
PR 1728	19306	Blue PE Med2174	050	14.80	13.40	15.60	32.10	29.90	35.50	581	15.13	14.70	15.90	32.03	30.50	34.20	587	14.45	13.90	15.20	33.13	31.80	34.30	585
PR 1744	19305	Blue PE Med2174	050	14.32	13.40	15.90	33.37	27.50	38.40	599	14.07	13.70	14.30	33.43	31.50	35.50	591	15.01	13.70	17.50	32.96	32.30	34.30	587
PR 1760	19304	Blue PE Med2174	050	14.68	13.90	16.10	32.59	30.30	35.40	602	15.60	14.20	17.20	34.61	32.90	36.90	590	15.83	14.10	17.10	33.00	30.20	35.10	596
PR 1776	19303	Blue PE Med2174	050	14.03	13.20	15.80	33.12	31.10	35.00	601	13.70	13.10	14.30	30.93	28.40	33.00	587	14.81	13.50	16.90	30.97	28.50	33.50	581
PR 1791	19302	Blue PE Med2174	050	15.08	13.90	17.40	32.04	29.00	36.00	581	15.07	14.40	15.90	30.77	27.90	34.30	581	15.67	14.60	16.70	30.82	28.30	34.90	577
PR 1806	19301	Blue PE Med2174	050	14.70	14.00	15.00	32.36	31.90	33.00	598	14.17	13.90	14.60	32.44	30.10	34.10	585	14.47	13.20	15.80	32.46	31.00	33.30	590
PR 1821	19300	Blue PE Med2174	050	14.26	12.70	16.00	32.70	29.00	36.80	609	16.23	14.70	18.80	32.74	30.40	34.10	587	14.14	13.30	15.10	31.28	28.40	34.40	594
PR 1837	19299	Blue PE Med2174	050	13.44	12.40	15.20	33.22	29.20	36.70	609	14.60	13.70	15.30	29.40	27.50	30.90	591	15.08	13.90	16.50	33.12	30.30	36.70	604
PR 1853	19298	Blue PE Med2174	050	14.31	13.00	15.50	32.10	25.60	36.70	589	14.23	13.40	15.40	33.77	30.90	37.00	595	14.78	14.20	15.60	32.76	31.50	34.90	589
PR 1869	19297	Blue PE Med2174	050	13.48	13.00	14.10	31.92	28.40	34.10	596	14.97	14.70	15.40	32.22	31.00	33.10	592	14.69	14.00	15.70	32.18	31.00	33.80	589
PR 1885	19296	Blue PE Med2174	050	13.48	13.10	14.00	33.03	28.50	34.80	598	14.87	14.40	15.30	32.71	29.90	35.90	597	15.78	14.10	16.20	32.50	31.20	36.10	578
PR 1902	19295	Blue PE Med2174	050	14.21	13.20	16.60	32.37	29.90	35.90	592	15.57	12.70	17.60	32.60	30.30	35.40	595	14.73	13.90	16.10	32.14	30.00	35.40	581
PR 1917	19294	Blue PE Med2174	050	14.01	13.20	14.90	31.68	28.30	37.10	607	14.50	13.60	15.10	30.56	29.30	32.20	589	14.91	13.90	16.70	32.06	30.20	35.50	596
PR 1934	19293	Blue PE Med2174	050	14.07	13.50	16.50	34.62	31.20	38.70	595	13.67	13.20	14.40	31.89	30.70	33.80	600	15.16	14.40	16.60	32.40	30.50	34.50	591
PR 1949	19292	Blue PE Med2174	050	14.61	13.00	17.30	34.29	31.30	37.60	608	14.57	14.30	14.90	32.58	30.00	36.20	580	14.25	13.10	15.40	31.47	30.20	32.30	586
PR 1964	19291	Blue PE Med2174	050	14.02	13.10	15.20	34.10	28.80	38.80	601	14.73	13.60	16.90	32.61	30.30	34.20	588	14.59	13.40	16.82	31.56	30 20	33.80	596

				Dye							Intermediate							Measure						
				Knot			Straight				Knot			Straight				Knot			Straight			
Bates	Batch	Product	Size	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter
PR 1979	19290	Blue PE Med2174	050	14.30	12.90	16.60	31.78	28.80	35.20	608	15.13	14.20	16.30	32.43	30.20	35.20	591	14.77	13.70	16.30	32.96	31.10	34.80	588
PR 1995	19289	Blue PE Med2174	050	14.40	13.50	15.60	32.26	31.10	38.50	614	15.43	14.40	17.00	33.77	31.50	35.70	602	15.47	14.00	16.70	33.30	29.00	37.50	582
PR 2011	19288	Blue PE Med2174	050	14.29	12.50	15.70	31.68	30.00	33.20	599	15.50	15.20	15.70	31.49	25.90	34.90	599	16.62	14.60	18.30	32.08	28.40	34.80	578
PR 2026	19287	Blue PE Med2174	050	16.34	14.90	18.20	34.00	29.60	37.90	606	15.60	15.30	15.80	33.36	30.30	35.60	585	15.33	13.50	18.50	32.73	30.30	35.90	595
PR 2041	19286	Blue PE Med2174	050	14.98	13.90	16.50	32.24	30.00	35.40	606	15.87	14.20	18.60	33.16	29.90	36.50	581	14.97	13.80	16.70	33.18	31.40	36.60	587
PR 2056	19285	Blue PE Med2174	050	14.28	13.30	15.80	33.62	29.40	36.70	607	15.33	13.90	16.30	33.57	30.40	36.30	588	15.10	13.20	17.70	30.75	28.00	33.30	591
PR 2071	19284	Blue PE Med2174	050	15.03	13.10	18.00	32.60	30.70	35.00	603	13.73	12.50	14.40	31.49	28.20	34.80	590	14.23	12.30	18.10	32.57	29.40	36.50	588
PR 2086	19283	Blue PE Med2174	050	14.06	13.20	15.60	31.80	30.30	33.50	611	15.43	14.70	16.70	32.87	30.00	36.30	594	15.09	14.50	16.80	32.83	30.90	35.10	591
PR 2101	19282	Blue PE Med2174	050	14.79	13.00	16.30	28.62	20.70	34.10	610	15.83	15.10	16.30	33.00	30.50	36.20	585	14.59	13.20	17.00	32.20	30.60	33.70	589
PR 2117	19220	Blue PE Med2174	050	15.48	14.10	18.30	32.36	30.30	37.00	603	14.97	13.80	16.50	31.87	25.70	38.70	591	13.95	13.20	15.00	33.62	32.20	36.50	594
PR 2132	19219	Blue PE Med2174	050	14.80	12.70	16.20	30.22	27.00	32.70	615	14.53	14.20	14.90	31.91	29.90	35.70	593	16.30	14.60	18.50	33.69	30.10	37.50	593
PR 2147	19218	Blue PE Med2174	050	14.10	11.20	15.90	31.22	27.80	36.10	602	16.07	14.70	17.40	35.21	33.90	36.60	580	15.13	13.50	16.10	31.77	30.20	36.10	582
PR 2162	19217	Blue PE Med2174	050	14.20	12.10	16.20	31.64	29.30	36.30	596	15.50	13.80	16.50	32.72	29.30	36.30	588	15.17	13.10	17.40	31.83	28.90	34.40	585
PR 2177	19216	Blue PE Med2174	050	14.53	12.90	16.40	33.96	29.40	37.60	594	14.63	13.30	15.90	31.14	28.50	33.20	584	14.62	13.00	16.20	31.93	28.80	34.50	573
PR 2194	19215	Blue PE Med2174	050	14.32	13.20	15.70	32.12	28.00	37.80	591	14.40	13.30	16.10	32.34	30.40	35.20	594	15.94	14.30	18.60	31.94	28.80	35.10	588
PR 2209	19214	Blue PE Med2174	050	14.28	13.20	15.80	33.59	31.70	35.40	595	15.70	14.90	16.70	32.31	30.80	34.40	600	15.91	14.20	17.81	31.72	28.00	34.00	585
PR 2225	19213	Blue PE Med2174	050	14.30	13.10	15.40	31.02	29.30	33.00	589	16.30	14.20	18.70	32.98	30.60	35.40	594	16.37	14.70	18.10	32.07	29.50	34.20	582
PR 2240	19212	Blue PE Med2174	050	15.41	13.70	16.50	32.84	30.00	35.30	602	14.87	14.40	15.50	33.24	29.40	36.20	593	15.41	13.40	19.10	31.71	29.00	35.30	596
PR 2257	19211	Blue PE Med2174	050	13.96	12.40	16.00	33.17	30.80	36.60	599	14.87	14.60	15.20	32.40	30.40	36.60	587	14.37	12.90	17.10	31.54	29.40	33.50	588
PR 2275	19210	Blue PE Med2174	050	13.76	12.70	14.50	33.73	29.90	37.70	600	15.47	14.20	17.00	33.10	30.00	37.20	593	13.71	12.30	16.00	31.17	28.30	32.90	592
PR 2290	19209	Blue PE Med2174	050	13.54	12.40	15.30	33.21	30.50	36.20	603	16.03	13.90	17.90	33.13	31.50	35.40	589	14.39	12.70	15.90	33.13	30.30	35.60	587
PR 2305	19207	Blue PE Med2174	050	14.21	12.60	16.40	34.20	31.10	36.10	597	14.43	13.60	15.20	32.34	31.20	33.70	592	14.00	12.90	16.20	32.67	29.50	34.70	590
PR 2321	19206	Blue PE Med2174	050	14.31	12.10	16.20	32.87	29.00	35.90	614	14.60	13.90	15.10	32.82	31.00	34.80	598	14.27	12.40	16.50	32.28	30.60	34.50	588
PR 2337	19279	Blue PE Med2174	050	14.34	13.30	15.20	33.47	30.00	37.40	607	15.87	14.40	17.50	31.78	29.80	35.10	597	15.48	13.50	18.20	34.29	33.30	37.50	586
PR 2354	19278	Blue PE Med2174	050	14.50	13.70	16.00	34.07	31.10	38.10	619	15.47	14.20	16.20	33.53	30.70	37.70	584	15.69	13.90	16.90	32.62	30.20	34.90	590
PR 2370	19277	Blue PE Med2174	050	14.68	13.40	16.20	32.81	29.20	36.50	597	15.77	14.40	16.30	32.76	30.60	35.30	598	15.87	14.50	16.00	33.44	32.20	34.60	588
PR 2385	19276	Blue PE Med2174	050	15.14	13.30	17.10	32.87	28.80	35.10	622	15.93	14.80	16.50	31.26	37.00	34.30	581	14.55	13.40	16.10	31.47	29.40	34.70	580
PR 2401	19275	Blue PE Med2174	050	15.13	13.40	16.30	32.98	29.50	37.60	616	14.73	13.70	16.50	33.66	30.30	38.50	591	14.56	13.00	17.10	33.96	31.90	39.50	587
PR 2417	19274	Blue PE Med2174	050	14.69	14.10	15.70	33.00	30.60	35.30	616	16.50	17.90	19.50	35.51	31.60	38.90	582	15.32	13.10	16.10	32.01	29.00	34.30	586
PR 2433	19273	Blue PE Med2174	050	14.56	14.00	15.60	32.94	30.20	36.50	591	15.33	14.40	15.80	31.94	30.70	34.00	585	14.87	14.10	16.10	33.67	32.10	35.10	590
PR 2449	19272	Blue PE Med2174	050	13.08	11.90	14.10	32.60	30.90	34.80	603	15.33	13.60	17.70	32.57	30.40	35.70	594	16.79	15.30	18.60	32.52	29.50	38.80	584
PR 2466	17945	Blue PE Med2174	050	14.31	13.10	15.80	33.59	30.30	37.00	599	14.77	13.70	16.30	30.74	27.00	33.20	585	14.82	13.20	16.20	31.28	28.00	34.30	582
PR 135	17943	Blue PE Med2174	050	14.64	13.20	16.70	34.11	30.90	37.50	597	14.07	13.10	14.90	33.26	29.80	36.60	583							
PR 148	17723	Blue PE Med2174	050	14.70	13.20	16.60	31.73	28.10	39.10	582	13.87	13.10	14.60	33.12	31.10	35.90	582							
PR 2483	17619	Blue PE Med2174	050	13.50	12.60	14.90	32.77	29.80	36.80	584	15.13	14.40	15.90	34.00	31.30	40.10	562	14.95	14.00	16.70	34.09	30.50	37.40	589
PR 2497	17486	Blue PE Med2174	050	15.03	13.50	16.40	33.12	29.40	37.70	599	15.63	14.60	16.40	33.44	29.50	38.20	582	15.36	13.80	17.10	31.89	28.60	35.40	572
PR 2512	17485	Blue PE Med2174	050	14.71	12.70	16.40	32.66	30.30	37.00	596	14.20	13.90	14.50	33.84	30.30	35.90	573	14.75	13.50	16.30	33.59	32.20	35.30	589
PR 2528	17417	Blue PE Med2174	050	13.84	12.50	16.80	34.98	32.10	37.20	590	13.63	12.40	14.30	33.20	29.00	36.80	584	14.99	13.50	16.70	33.59	31.80	35.60	586
PR 160	17231	Blue PE Med2174	050	13.74	12.60	16.20	33.69	28.50	39.70	597	14.57	12.40	15.70	32.00	28.00	34.80	585							
PR 176	17230	Blue PE Med2174	050	13.97	12.70	16.10	32.50	26.00	35.00	593	14.13	12.90	15.00	33.10	29.20	34.70	583							
PR 194	17229	Blue PE Med2174	050	15.32	13.20	16.60	34.27	30.90	36.50	599	14.13	13.40	14.50	31.69	29.40	34.30	574							
PR 211	17228	Blue PE Med2174	050	15.24	14.20	16.20	32.33	29.80	35.00	593	15.30	14.90	15.80	32.22	28.70	35.70	575							
PR 2541	17180	Blue PE Med2174	050	15.20	13.70	16.20	34.94	33.10	38.60	586	14.63	14.20	15.20	34.22	32.30	36.50	586	14.70	13.10	16.00	33.13	29.80	34.60	586
PR 2556	16834	Blue PE Med2174	050	14.04	12.50	15.70	32.32	27.50	36.40	602	15.97	14.70	17.30	30.72	27.90	34.80	583	15.64	13.60	18.20	29.51	25.10	34.90	580
PR 2570	16833	Blue PE Med2174	050	14.03	12.80	15.10	31.91	29.30	35.40	577	15.67	15.30	16.20	33.42	30.90	36.80	576	15.77	13.50	19.00	32.58	30.20	36.90	576
PR 2585	16832	Blue PE Med2174	050	14.97	13.70	16.40	31.49	27.40	35.30	599	15.63	15.10	16.60	30.62	26.70	34.90	587	14.13	13.20	16.10	32.53	29.20	35.30	588
PR 2602	16831	Blue PE Med2174	050	14.01	12.90	15.80	32.59	28.10	36.60	586	15.93	15.00	17.00	34.06	29.00	38.30	581	15.07	12.90	16.40	32.42	29.80	34.30	581
PR 2617	16830	Blue PE Med2174	050	13.60	13.20	14.00	32.66	29.60	36.90	592	15.47	13.80	16.90	31.20	26.80	34.50	585	15.73	14.60	18.00	34.61	32.30	37.10	583
PR 2631	16829	Blue PE Med2174	050	14.11	13.00	15.40	33.66	29.40	39.20	588	15.00	14.20	15.40	32.82	28.40	37.60	579	15.23	13.30	16.50	32.31	29.30	33.80	571
PR 2646	16828	Blue PE Med2174	050	14.58	13.50	15.70	31.86	29.20	39.10	596	15.27	14.60	16.20	32.23	29.10	34.70	572	14.52	12.60	18.20	33.45	30.90	38.20	581
PR 2660	16826	Blue PE Med2174	050	13.53	13.00	14.80	33.30	28.90	37.10	585	15.23	14.70	15.60	33.42	30.30	36.00	568	15.00	13.40	16.70	33.74	29.40	39.70	568
PR 2676	16825	Blue PE Med2174	050	14.90	13.40	16.70	32.97	28.70	35.30	601	14.40	13.50	15.20	32.79	30.20	33.90	576	14.53	13.50	16.00	32.49	29.30	36.70	580
PR 2690	16824	Blue PE Med2174	050	13.63	12.90	14.70	35.26	32.60	38.90	586	15.40	14.80	16.60	32.63	29.40	35.70	568	14.55	13.30	16.10	33.11	29.90	35.10	581
PR 2704	16823	Blue PE Med2174	050	14.45	13.10	16.20	33.32	29.90	36.70	570	13.60	12.70	14.60	32.97	29.40	36.00	583	15.48	13.40	17.70	33.34	30.10	36.90	592
PR 2721	16822	Blue PE Med2174	050	14.41	13.40	15.70	34.27	29.30	37.90	577	14.60	13.60	15.70	33.21	28.90	37.40	568	15.00	13.20	18.60	34.30	30.40	38.70	585
PR 2736	16821	Blue PE Med2174	050	13.43	12.70	14.70	33.38	31.00	37.70	475	16.43	15.20	18.60	34.51	28.60	37.40	567	15.25	13.40	17.10	33.33	31.90	35.70	582
PR 2751	16590	Blue PE Med2174	050	14.24	13.20	16.20	35.47	39.50	41.10	568	14.63	13.60	16.70	32.85	27.90	36.30	562	14.19	12.30	16.00	31.03	29.60	32.20	585
PR 2767	16589	Blue PE Med2174	050	14.57	13.90	15.60	33.69	31.50	36.40	574	16.53	16.20	16.70	33.86	32.30	35.50	594	14.39	13.20	15.30	33.46	32.00	34.50	573
PR 2782	16588	Blue PE Med2174	050	14.83	13.30	16.90	31.76	36.40	34.30	571	15.17	14.30	16.90	32.87	28.50	35.40	585	14.01	12.10	17.40	32.90	30.60	36.80	584
PR 2796	16587	Blue PE Med2174	050	14.41	12.70	16.10	35.19	31.40	39.80	563	14.63	13.20	17.40	32.66	31.30	34.30	584	14.17	13.10	15.20	33.77	31.70	37.00	576
PR 2810	16586	Blue PE Med2174	050	14.96	13.70	16.10	34.61	32.30	38.50	596	14.50	13.50	16.10	32.79	29.70	34.40	576	13.94	12.60	15.20	32.58	31.00	33.80	574
PR 2824	16585	Blue PE Med2174	050	14.59	12.90	15.70	36.27	31.50	40.00	605	14.67	13.00	17.20	33.53	30.00	38.10	562	14.42	13.10	16.20	31.63	29.20	35.00	568
PR 2838	16584	Blue PE Med2174	050	15.34	14.50	16.80	34.43	32.30	37.50	585	15.43	14.60	16.30	33.86	31.40	36.50	584	15.29	13.80	16.90	34.34	32.10	35.30	578
PR 2851	16582	Blue PE Med2174	050	15.33	13.20	17.50	36.60	32.60	40.90	593	16.23	15.40	17.60	33.60	32.20	35.80	589	15.02	13.50	16.80	34.20	31.10	35.80	580
PR 2867	16581	Blue PE Med2174	050	13.34	12.40	14.20	32.63	29.90	38.40	567	15.63	13.30	16.60	33.62	30.40	38.10	567	15.72	14.00	17.40	32.69	28.60	35.90	560
PR 2882	16580	Blue PE Med2174	050	14.60	13.20	16.80	31.59	29.00	35.10	569	14.37	13.90	15.30	33.59	29.90	37.10	562	15.23	13.50	17.20	31.58	28.10	36.10	570
PR 2898	16579	Blue PE Med2174	050	15.01	13.20	17.20	35.72	32.20	37.30	572	15.53	15.20	15.90	32.41	29.80	35.20	569	15.01	13.10	16.70	32.13	28.80	35.30	586

				Dye							Intermediate							Measure						
				Knot			Straight				Knot			Straight				Knot			Straight			
Bates	Batch	Product	Size	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter
PR 2910	16578	Blue PE Med2174	050	14.93	13.60	17.20	33.60	29.90	37.30	572	15.60	13.00	19.60	32.26	29.90	36.20	571	16.06	14.50	19.60	32.67	29.90	36.30	573
PR 2925	16577	Blue PE Med2174	050	13.80	13.10	15.40	33.82	28.70	37.40	568	14.93	13.80	16.00	32.94	30.10	35.40	565	15.62	13.50	18.10	33.91	30.80	35.40	567
PR 2940	16576	Blue PE Med2174	050	14.71	13.50	16.50	34.43	28.00	38.40	581	14.63	14.20	15.20	32.59	28.60	37.60	560	15.39	13.30	18.60	33.48	28.80	36.20	565
PR 237	16142	Blue PE Med2174	050	14.33	12.40	15.70	35.74	31.90	39.60	590	15.93	14.70	17.30	35.48	32.40	39.20	586							
PR 253	16141	Blue PE Med2174	050	14.78	12.90	17.10	30.09	27.30	32.40	569	13.60	12.30	15.00	32.67	30.40	37.40	572							
PR 268	16140	Blue PE Med2174	050	14.73	13.10	16.00	32.86	31.30	34.40	588	14.08	12.40	15.10	32.91	26.50	38.80	585							
PR 285	16125	Blue PE Med2174	050	14.81	13.20	17.40	34.06	30.90	37.00	594	13.20	12.70	13.60	31.38	29.30	33.60	584	0.14	0.12	0.16	0.19	0.18	0.19	66
PR 2955	16124	Blue PE Med2174	050	13.63	12.70	15.10	31.90	27.50	35.60	562	14.40	13.30	15.50	33.84	30.20	38.80	593	15.43	14.00	17.30	33.74	29.50	37.00	569
PR 2969	16123	Blue PE Med2174	050	14.31	13.20	16.10	32.26	28.20	37.80	568	14.07	12.70	15.10	33.62	31.90	35.60	586	15.45	13.40	17.20	32.60	28.80	36.80	567
PR 2984	16122	Blue PE Med2174	050	15.52	13.90	17.10	32.74	29.30	36.60	583	14.77	13.50	17.00	32.68	29.50	35.40	572	15.51	14.50	16.90	32.13	28.50	34.70	556
PR 3000	15439	Blue PE Med2174	050	13.92	13.10	14.80	31.11	26.90	35.00	656	14.77	14.10	15.90	32.18	28.80	34.00	573	15.37	14.20	16.70	33.39	31.90	34.80	571
PR 3014	15438	Blue PE Med2174	050	13.81	13.20	14.40	28.42	25.90	34.70	562	13.53	12.10	14.40	29.41	26.40	32.10	574	14.72	13.60	16.20	29.76	27.30	31.20	567
PR 3028	15404	Blue PE Med2174	050	15.00	13.50	17.20	29.74	25.70	32.90	569	14.63	14.10	15.20	29.78	25.90	32.60	583	15.16	14.50	16.00	31.63	29.90	33.70	585
PR 3043	15248	Blue PE Med2174	050	13.14	12.00	14.10	31.99	28.90	36.70	593	12.73	11.40	13.40	29.04	24.40	34.00	593	13.68	12.00	16.30	30.69	27.80	34.00	584
PR 304	15229	Blue PE Med2174	050	13.33	12.30	13.80	32.03	28.90	36.00	592	14.92	13.20	16.90	31.51	27.70	36.80	589							
PR 3059	15228	Blue PE Med2174	050	14.56	13.10	16.70	31.22	24.10	33.50	565	14.60	13.80	15.90	29.46	27.00	31.80	567	15.47	13.90	17.00	31.72	28.50	33.40	579
PR 3075	15227	Blue PE Med2174	050	13.93	12.54	15.10	32.11	29.70	33.90	568	15.60	14.90	16.20	31.02	28.60	35.10	573	14.28	12.30	16.20	30.23	26.10	33.40	579
PR 3090	15226	Blue PE Med2174	050	14.40	13.40	15.90	32.68	31.80	34.20	580	14.63	14.20	15.60	32.56	31.30	33.60	581	14.06	12.00	16.80	33.02	30.00	36.90	562
PR 3104	15225	Blue PE Med2174	050	13.98	12.30	15.40	31.73	27.70	35.20	586	14.20	13.70	15.10	31.90	28.40	35.30	577	14.07	13.00	15.50	31.57	30.10	33.50	573
PR 15	15089	Blue PE Med2174	050	13.54	12.10	15.40	32.07	28.60	34.60	576	14.03	12.50	14.80	28.77	27.00	31.10	571	14.94	13.90	17.30	31.13	27.10	34.40	575
PR 37	15030	Blue PE Med2174	050	13.54	12.10	15.40	32.07	28.60	34.60	576	14.03	12.50	14.80	28.77	27.00	31.10	571	15.22	13.20	16.60	31.24	27.60	33.10	571
PR 3118	15029	Blue PE Med2174	050	14.01	12.30	15.30	33.92	32.70	35.70	601	14.90	13.00	16.70	32.40	28.30	36.00	580	14.68	12.90	17.20	33.21	28.80	36.10	585
PR 3133	15028	Blue PE Med2174	050	14.16	13.00	16.60	29.78	25.80	33.30	593	14.83	14.20	15.50	31.98	29.60	33.90	575	15.24	13.70	17.30	29.69	25.00	34.30	590
PR 3149	14804	Blue PE Med2174	050	14.82	13.60	15.80	30.01	25.90	31.90	599	14.60	14.10	15.50	30.50	28.10	32.00	577	15.37	12.90	17.50	29.78	28.40	31.10	572
PR 321	14599	Blue PE Med2174	050	14.90	13.40	16.40	32.68	30.40	35.00	590	15.07	13.00	17.50	31.17	28.60	36.80	579							
PR 3164	14597	Blue PE Med2174	050	14.93	13.50	16.80	30.41	26.80	32.90	597	16.53	14.70	19.00	31.48	28.90	34.80	595	15.68	13.40	18.30	33.04	29.80	36.60	580
PR 373	14596	Blue PE Med2174	050	14.93	14.50	15.50	32.03	30.90	32.80	594	17.47	15.60	19.10	33.41	30.60	36.20	591							
PR 390	14588	Blue PE Med2174	050	13.68	12.70	14.90	29.82	26.70	35.60	576	13.77	13.40	14.20	30.87	28.40	33.70	571							
PR 413	14567	Blue PE Med2174	050	14.82	13.20	15.90	28.84	23.00	32.90	603	13.63	13.00	14.20	31.82	30.80	33.30	579							
PR 422	14507	Blue PE Med2174	050	14.00	13.20	15.60	31.88	28.30	35.70	569	16.90	16.20	17.30	32.24	29.90	34.80	593							
PR 3179	14504	Blue PE Med2174	050	13.59	12.30	16.20	29.48	25.10	31.70	591	14.50	13.90	15.40	30.59	28.80	32.60	584	14.73	13.00	16.30	30.73	27.90	34.20	586
PR 3194	14503	Blue PE Med2174	050	13.63	11.20	14.90	29.88	27.10	34.50	591	13.30	12.50	14.70	27.99	25.00	33.10	573	14.63	12.80	16.00	30.51	26.20	32.70	580
PR 3208	14502	Blue PE Med2174	050	14.06	13.10	15.20	29.33	26.60	32.20	584	15.07	14.20	15.90	30.27	27.00	31.80	581	14.43	13.20	15.70	30.24	27.60	32.80	574
PR 3222	14501	Blue PE Med2174	050	14.06	13.00	15.20	27.40	22.70	32.00	597	14.33	13.70	15.20	32.07	30.30	34.80	583	14.86	13.90	16.50	31.78	29.20	34.70	577
PR 3236	14500	Blue PE Med2174	050	14.32	13.50	16.60	28.23	22.70	32.30	591	14.17	13.90	14.60	30.60	27.20	33.20	571	13.83	12.90	15.00	32.09	28.50	35.30	584
PR 3251	14499	Blue PE Med2174	050	14.20	13.30	16.30	30.01	26.30	33.00	595	15.40	14.90	16.40	33.30	30.20	36.60	568	14.04	12.90	14.90	32.22	29.60	34.00	575
PR 3267	14489	Blue PE Med2174	050	14.37	12.20	15.60	33.07	29.40	34.80	589	14.47	14.30	14.70	32.91	29.40	35.30	599	14.16	12.50	15.50	32.02	29.30	34.90	581
PR 3282	14351	Blue PE Med2174	050	13.94	12.60	16.80	29.86	26.60	34.00	594	14.50	13.00	16.50	31.16	29.20	34.20	571	14.82	13.70	15.80	31.87	30.40	34.70	588
PR 3298	14350	Blue PE Med2174	050	15.43	14.20	16.70	30.52	26.60	34.20	604	14.93	12.90	16.50	31.53	29.90	33.30	574	14.82	13.50	17.20	31.79	29.80	34.60	576
PR 3313	14349	Blue PE Med2174	050	14.21	13.10	15.60	29.19	24.20	33.50	597	13.73	13.30	14.20	29.64	27.30	31.40	577	14.88	12.80	17.00	31.33	30.20	34.20	571
PR 3329	14348	Blue PE Med2174	050	14.88	13.40	16.10	32.73	29.10	36.40	607	15.23	13.70	16.10	31.51	28.40	35.40	577	14.72	12.30	16.60	30.13	27.60	33.10	580
PR 3345	14347	Blue PE Med2174	050	13.56	12.30	14.40	30.78	25.70	34.90	603	14.90	13.30	15.80	28.65	21.00	34.20	572	13.96	12.20	15.20	29.66	25.00	32.80	590
PR 3359	14346	Blue PE Med2174	050	15.63	14.50	16.60	32.42	31.10	35.20	585	15.43	14.60	16.50	31.21	29.10	32.70	594	14.48	12.30	16.10	33.40	31.20	37.00	580
PR 3374	14345	Blue PE Med2174	050	14.58	13.60	15.60	32.16	28.30	35.00	579	15.47	14.70	16.30	32.56	28.90	35.90	591	14.67	13.00	17.80	32.21	28.20	36.20	576
PR 3390	14343	Blue PE Med2174	050	15.51	14.50	16.40	32.18	27.50	36.10	574	15.33	14.70	15.90	33.92	30.40	37.30	576	14.62	13.00	15.90	33.44	29.70	37.50	577
PR 3405	14342	Blue PE Med2174	050	13.46	11.84	15.54	21.97	20.85	22.74	596	15.23	14.00	16.80	32.64	29.90	36.60	571	14.58	12.40	17.00	31.23	28.80	33.90	591
PR 3419	14341	Blue PE Med2174	050	14.14	13.50	15.80	33.19	28.40	36.00	592	15.13	13.30	16.20	33.88	30.90	36.30	588	13.82	12.30	14.70	31.13	28.20	34.30	586
PR 3435	14340	Blue PE Med2174	050	13.94	12.70	15.60	31.84	28.10	34.10	565	13.83	13.40	14.30	31.78	30.20	33.40	600	14.92	13.60	15.60	31.08	29.20	35.10	575
PR 3451	14339	Blue PE Med2174	050	14.84	12.70	17.20	31.63	28.30	35.20	608	14.70	14.30	15.10	33.48	29.90	35.90	576	15.57	14.00	17.40	32.63	30.40	34.90	573
PR 3468	14338	Blue PE Med2174	050	14.14	12.05	15.58	20.76	18.27	22.09	602	15.03	13.90	16.20	30.40	23.90	34.40	579	13.58	11.90	16.70	30.86	28.50	34.20	591
PR 3484	14197	Blue PE Med2174	050	14.37	13.20	15.62	22.45	20.37	24.94	590	14.18	13.82	14.58	19.03	17.01	20.99	583	15.01	13.82	17.06	21.59	19.92	23.28	549
PR 3498	13818	Blue PE Med2174	050	14.46	13.29	16.38	22.03	20.75	24.04	586	15.02	14.37	15.73	20.43	18.06	22.88	563	14.32	13.06	15.59	20.98	20.34	22.47	570
PR 3512	13186	Blue PE Med2174	050	13.46	12.86	13.89	26.04	25.86	26.13	574	13.77			22.75	22.08	23.95	598	14.51	12.92	16.62	23.44	22.08	24.64	567
PR 3520	13029	Blue PE Med2174	050	14.24	13.46	15.65	23.46	21.59	25.03	591	14.61	13.90	15.94	21.51	18.00	34.37	566	14.13	13.05	14.88	20.46	19.14	21.39	591
PR 3534	13028	Blue PE Med2174	050	14.24	13.03	15.34	21.58	19.49	23.17	575	13.25	12.95	13.62	18.66	15.88	20.99	601	14.12	13.30	15.50	22.92	16.25	35.85	569
PR 3548	13027	Blue PE Med2174	050	13.98	13.32	14.91	22.34	21.47	23.54	559	14.53	13.73	15.92	20.76	18.64	22.02	599	13.67	12.57	14.49	20.47	19.01	21.80	578
PR 3563	13026	Blue PE Med2174	050	13.78	12.41	15.02	22.73	20.89	25.16	567	14.43	14.03	14.74	21.65	18.67	26.20	602	14.54	13.64	15.30	20.37	19.19	21.54	603
PR 3577	13011	Blue PE Med2174	050	14.52	14.09	15.62	23.29	21.79	25.42	598	13.86	13.05	14.56	21.93	20.83	23.62	567	14.15	13.44	14.96	19.21	17.25	20.47	590
PR 5341	12380	Blue PE Med2174	050	15.06	14.23	16.25	25.69	21.06	33.61	607	14.46	14.02	14.75	18.15	12.33	29.35	573	14.27	13.65	15.08	19.37	15.84	21.48	591
PR 5357	12378	Blue PE Med2174	050	14.74	14.00	15.76	22.99	21.80	24.67	579								14.22	13.72	14.95	18.64	16.31	21.47	584
PR 5371	12377	Blue PE Med2174	050	14.98	14.28	16.20	23.24	21.20	25.66	604	15.22	14.92	15.72	22.76	21.15	25.73	592	14.72	13.98	17.08	22.00	19.59	23.78	591
PR 5386	12376	Blue PE Med2174	050	14.61	14.22	15.58	22.07	21.06	23.66	591	15.76	13.99	16.03	23.30	21.32	25.21	565	14.96	14.30	16.94	22.17	21.19	24.29	591
PR 5403	12375	Blue PE Med2174	050	14.41	13.94	15.36	21.45	20.64	22.36	572	15.16	14.10	16.62	22.14	19.76	26.54	595	15.75	14.35	19.87	23.99	22.21	26.87	584
PR 5418	12374	Blue PE Med2174	050	14.69	14.00	15.67	22.71	20.36	24.68	567	15.64	15.18	15.93	22.30	20.11	24.46	576	14.08	12.52	15.98	22.34	20.66	24.70	593
PR 5442	12101	Blue PE Med2174	050	13.44	12.03	15.10	20.54	16.52	22.84	602	13.11	12.25	14.18	15.53	11.72	17.94	571	14.16	11.62	16.32	17.38	14.63	20.55	591
PR 5458	12100	Blue PE Med2174	050	12.97	10.93	14.33	22.12	19.64	24.21	597	14.00	13.36	14.60	19.70	17.07	23.15	581	14.62	12.50	16.53	21.15	18.36	22.52	586
PR 5474	11962	Blue PE Med2174	050	14.11	11.82	15.90	22.92	19.26	28.34	584														

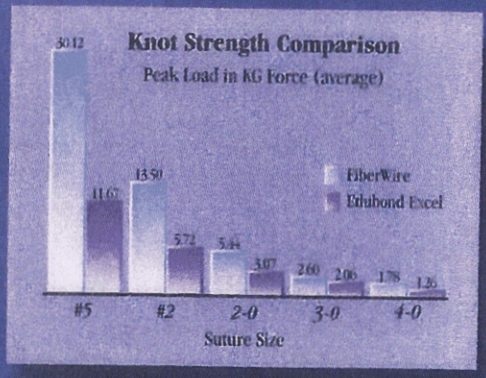
				Dye							Intermediate							Measure						
				Knot			Straight				Knot			Straight				Knot			Straight			
Bates	Batch	Product	Size	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter	Avg	Min	Max	Avg	Min	Max	Diameter
PR 5484	11961	Blue PE Med2174	050	13.88	12.14	15.98	20.90	18.09	23.94	614	14.33	13.50	15.37	21.17	19.62	22.41	573	14.15	12.01	16.08	19.53	15.56	22.88	584
PR 5501	11960	Blue PE Med2174	050	14.02	12.75	15.90	22.20	20.50	23.73	617	14.37	13.08	15.95	19.89	15.85	22.78	594	14.47	12.40	17.51	20.47	16.31	23.39	590
PR 5159	11959	Blue PE Med2174	050	13.66	12.39	15.24	22.00	20.24	24.75	620	14.69	12.44	17.02	22.25	19.91	24.45	588	14.30	12.96	16.94	19.74	14.22	25.75	580
PR 5175	11901	Blue PE Med2174	050	14.39	13.76	15.90	21.15	19.30	23.41	587	13.37	12.79	14.01	18.02	15.64	20.19	568	15.12	14.52	16.51	21.53	18.85	23.84	578
PR 5190	11854	Blue PE Med2174	050	15.09	12.93	16.69	23.22	22.16	23.99	570	14.97	14.22	15.39	20.44	4.66	23.83	578	14.49	12.99	15.72	20.85	16.71	25.11	579
PR 5205	11853	Blue PE Med2174	050	13.31	11.06	14.37	21.42	19.60	23.27	580	14.68	14.45	14.87	20.07	16.38	21.98	559	14.56	12.93	17.07	20.40	18.82	24.54	574
PR 5221	11852	Blue PE Med2174	050	14.77	13.49	17.26	23.03	21.61	24.34	621	10.35	5.14	15.55	20.24	18.45	21.93	549	13.72	13.04	14.64	18.70	15.04	21.69	575
PR 5235	11851	Blue PE Med2174	050	14.43	12.46	17.68	21.05	19.20	23.24	618	14.39	13.95	14.83	20.39	19.46	21.52	555	14.39	10.87	16.42	21.28	19.59	22.78	573
PR 5249	11850	Blue PE Med2174	050	14.13	13.26	15.38	22.84	21.59	24.18	584	14.66	13.87	15.17	21.86	20.65	23.31	577	13.70	11.99	15.13	18.08	16.47	19.81	584
PR 5264	11849	Blue PE Med2174	050	12.59	11.36	13.93	20.06	17.49	22.01	626	15.15	14.55	15.59	20.05	17.59	21.53	574	14.85	13.30	16.19	20.77	16.98	24.05	556
PR 5281	11848	Blue PE Med2174	050	13.72	11.47	15.92	23.08	20.54	25.29	612	14.32	14.28	14.39	20.80	18.38	22.35	570	13.28	11.55	14.97	18.42	17.42	19.85	563
PR 5296	11847	Blue PE Med2174	050	13.71	12.61	14.90	23.45	21.98	27.29	614	15.21	13.78	16.65	21.48	19.00	23.77	574	14.73	13.42	16.47	21.13	19.16	23.08	584
PR 5311	11846	Blue PE Med2174	050	13.53	12.04	14.51	20.96	19.31	22.59	610	14.83	14.10	16.19	20.77	18.91	22.79	594	13.64	12.05	15.08	20.25	17.14	21.94	568
PR 5326	11845	Blue PE Med2174	050	13.22	12.42	15.01	22.00	20.04	23.98	609	12.97	11.79	15.45	19.65	15.07	26.32	553	14.48	13.13	15.89	20.05	17.33	21.94	548
PR 4929	10998	Blue PE Med2174	050	12.06	11.43	12.59	22.89	21.67	24.73	542	12.35	11.16	13.18	22.04	18.04	24.59	584	12.13	10.71	12.99	22.75	20.04	24.02	554
PR 4944	10995	Blue PE Med2174	050	12.95	12.13	14.30	24.19	23.15	25.57	566	11.94	11.75	12.06	23.60	22.66	24.93	558	12.05	9.86	13.42	23.38	21.29	25.25	554
PR 4959	10994	Blue PE Med2174	050	12.27	10.92	13.71	23.78	21.58	25.20	554	12.09	11.24	13.16	22.99	21.11	24.86	555	12.64	11.28	14.10	22.70	19.85	24.06	543
PR 4976	10993	Blue PE Med2174	050	11.84	10.23	12.95	23.65	22.18	24.33	554	11.53	10.80	11.97	22.61	20.30	24.78	583	12.66	10.37	13.82	23.27	21.68	24.26	561
PR 50	10145	Blue PE Med2174	050	12.54	11.94	13.25	23.76	22.94	24.35	596	12.87	12.66	13.07	23.22	21.87	24.47	575	13.58	13.01	14.88	23.76	21.41	26.21	578
PR 84	10144	Blue PE Med2174	050	12.76	9.90	15.21	22.53	21.06	23.65	605	12.97	12.94	12.99	22.92	19.88	23.88	571	12.30	10.31	13.63	22.88	21.09	26.35	561
PR 4991	09983	Blue PE Med2174	050	12.10	10.62	12.58	24.06	23.00	25.27	597	12.90	12.66	13.07	23.60	22.18	24.32	564	12.62	11.14	14.38	23.21	22.01	24.28	568
PR 5007	09982	Blue PE Med2174	050	12.28	10.89	13.76	23.57	22.50	24.32	591	12.12	11.58	13.19	22.81	21.04	24.47	602	13.06	11.96	14.36	23.82	23.37	24.62	573
PR 5022	09981	Blue PE Med2174	050	12.26	10.55	13.49	23.87	22.22	25.54	610	11.98	11.89	12.05	21.71	18.72	24.76	573	12.95	11.73	14.38	22.57	20.32	23.71	568
PR 5037	09980	Blue PE Med2174	050	12.85	11.39	14.00	24.05	21.43	25.35	595	11.74	11.06	12.42	22.51	20.12	24.52	601	12.53	10.87	14.08	21.09	19.26	24.18	563
PR 5052	09659	Blue PE Med2174	050	11.73	10.67	13.58	23.39	22.35	25.06	611	11.38	10.71	12.27	22.34	19.46	23.59	585	12.81	11.60	14.05	22.65	21.01	24.94	579
PR 5068	09658	Blue PE Med2174	050	11.78	10.94	13.27	23.24	21.27	25.05	593	12.67	10.39	14.24	22.60	21.57	24.50	572	12.93	12.02	14.31	22.77	21.80	23.54	583
PR 5084	09657	Blue PE Med2174	050	12.10	11.06	13.01	23.64	21.00	25.22	596	10.03	9.45	10.48	22.15	20.99	22.89	572	12.65	11.62	13.58	22.06	18.62	25.60	576
PR 5099	09656	Blue PE Med2174	050	12.21	11.41	12.65	23.84	23.25	24.55	601	12.27	9.94	13.72	22.11	19.74	24.24	573	12.31	9.67	14.42	22.90	21.53	24.17	570
PR 5114	09620	Blue PE Med2174	050	11.79	10.33	13.45	21.75	17.26	24.38	606	12.49	12.18	12.86	20.62	17.73	23.86	576	12.32	11.37	13.06	22.49	22.02	22.87	575
PR 5129	09419	Blue PE Med2174	050	12.06	11.02	12.71	24.06	22.61	26.56	598	12.08	11.62	12.48	21.84	19.02	23.30	567	12.66	11.75	15.55	22.77	20.95	23.56	568
PR 5144	09306	Blue PE Med2174	050	12.64	11.52	13.62	23.51	21.95	24.70	597	12.85	11.06	13.96	23.34	21.53	24.77	566	12.97	11.77	13.76	22.63	21.36	24.43	586
PR 4696	09305	Blue PE Med2174	050	12.09	11.13	13.65	23.35	22.17	24.42	605	12.73	11.21	13.76	21.03	18.63	23.18	571	12.90	11.32	13.86	22.88	17.65	25.00	576
PR 4711	09304	Blue PE Med2174	050	12.27	11.45	13.58	22.20	18.45	24.43	603	12.50	11.63	13.12	21.62	18.21	23.76	568	12.96	11.82	14.55	23.19	21.70	23.97	562
PR 78	09204	Blue PE Med2174	050	12.30	11.48	14.13	22.96	20.33	24.72	601	12.91	12.63	13.17	22.88	21.47	24.37	564	11.49	10.18	12.35	20.34	18.02	22.35	550
PR 4728	08905	Blue PE Med2174	050	12.44	11.10	13.61	21.81	18.17	25.86	592	13.08	12.72	13.50	24.01	18.05	27.87	563	13.36	12.08	14.73	23.70	21.13	25.58	561
PR 4741	08330	Blue PE Med2174	050															13.58	12.08	15.31	27.31	23.95	29.08	570
PR 92	08203	Blue PE Med2174	050	12.60	11.63	13.31	22.79	20.87	24.35	609	13.32	12.85	13.80	21.79	19.18	23.02	575	13.22	11.86	15.52	23.38	20.27	25.15	576
PR 106	08202	Blue PE Med2174	050	12.69	11.17	13.70	22.68	15.27	26.42	592	13.21	12.62	13.76	24.00	19.15	28.18	577	12.53	11.11	14.30	21.51	19.81	25.55	572
PR 121	08201	Blue PE Med2174	050	12.77	11.86	13.76	23.98	20.00	27.05	599	13.41	12.83	13.80	21.27	19.01	24.18	565	12.61	10.61	14.67	20.58	17.73	22.40	576
PR 4748	08036	Blue PE Med2174	050	11.54	10.63	12.85	22.22	20.03	23.42	598	13.26	12.87	13.65	22.91	22.22	23.71	558	13.20	11.91	14.86	22.45	20.37	25.05	585
PR 4763	08035	Blue PE Med2174	050	12.66	11.41	14.80	24.93	22.13	29.87	599	12.98	12.30	13.51	22.16	19.96	23.72	557	13.46	11.90	17.00	23.56	21.27	28.53	583
PR 4778	08006	Blue PE Med2174	050	12.78	11.88	16.15	24.59	23.67	26.22	582	12.34	12.07	12.62	21.88	19.26	24.13	558	12.47	11.21	13.58	23.22	21.33	24.75	553
PR 4793	08005	Blue PE Med2174	050	11.91	10.58	13.13	23.72	21.30	25.43	583	12.90	12.65	13.16	22.42	18.82	24.46	562	12.06	10.51	14.18	23.04	21.92	24.38	557
PR 4808	08004	Blue PE Med2174	050	11.83	10.56	13.00	22.92	22.08	23.96	586	12.84	12.62	13.08	22.72	21.62	24.70	558	12.22	11.25	13.48	22.11	20.61	23.52	577
PR 4824	08003	Blue PE Med2174	050	13.23	12.57	13.81	23.59	22.38	25.10	589	13.37	12.62	13.85	21.63	18.78	23.88	575	12.39	9.97	13.45	20.43	17.38	23.65	583
PR 4840	08002	Blue PE Med2174	050	12.79	11.70	15.13	23.58	22.21	24.70	581	14.13	13.85	14.56	22.42	21.25	23.13	558	13.22	11.07	14.73	22.77	17.60	24.80	563
PR 4855	08001	Blue PE Med2174	050	12.93	11.85	15.12	23.85	21.47	25.61	587	13.71	13.08	14.03	22.46	20.85	24.57	562	13.18	12.17	14.52	23.85	21.18	26.66	565
PR 4870	08000	Blue PE Med2174	050	12.42	9.85	13.37	23.41	20.77	25.33	592	11.79	9.97	12.98	21.58	19.22	24.06	574	12.83	11.72	13.62	23.03	20.52	24.07	576
PR 4884	07999	Blue PE Med2174	050	11.67	9.85	12.37	22.98	19.57	24.98	586	12.22	11.85	12.42	22.96	20.23	24.42	577	13.40	12.97	14.06	22.25	19.80	25.12	584
PR 4899	07998	Blue PE Med2174	050	12.54	12.00	12.87	23.69	22.45	25.62	591	12.78	12.10	13.22	22.51	21.10	24.11	578	12.77	11.83	13.93	22.20	19.37	23.28	563
PR 4915	07997	Blue PE Med2174	050	12.16	10.73	13.05	23.51	21.16	25.10	591	12.86	12.53	13.10	22.06	20.21	24.00	578	12.16	10.51	13.41	21.28	19.27	23.77	577
PR 4513	07996	Blue PE Med2174	050	12.39	10.90	14.42	22.14	17.96	25.22	591	11.89	10.58	13.33	23.74	20.86	26.70	593	13.10	11.86	14.38	23.76	20.81	25.68	592
PR 4531	07995	Blue PE Med2174	050	11.99	11.07	13.11	23.13	19.67	25.86	595	13.15	11.58	14.15	22.41	20.90	25.52	571	13.34	12.03	14.26	23.06	20.38	26.68	587
PR 4548	07994	Blue PE Med2174	050	12.05	10.22	14.13	24.64	22.57	27.16	599	12.41	11.75	12.83	23.92	19.33	29.46	585	12.86	12.00	14.25	23.70	20.10	28.00	587
PR 4567	07992	Blue PE Med2174	050	12.09	11.88	13.92	22.00	20.30	25.41	614	13.21	12.43	14.23	22.30	20.52	27.96	560	13.16	12.15	14.42	24.59	23.06	26.27	578
PR 4586	07991	Blue PE Med2174	050	12.06	11.01	12.93	18.65	15.42	20.20	611	12.25	11.97	12.52	20.17	18.55	23.32	586	12.97	11.03	14.75	21.74	19.68	24.00	563
PR 4605	07990	Blue PE Med2174	050	12.35	11.20	13.58	22.86	18.11	26.26	605	12.84	11.41	14.10	20.41	17.63	26.45	576	12.93	10.82	15.37	22.26	21.01	24.11	587
PR 4622	07943	Blue PE Med2174	050	11.76	10.57	13.10	20.69	18.61	23.51	608	13.00	12.03	13.60	24.11	20.66	27.25	566	13.08	11.98	14.10	22.59	19.56	28.17	577
PR 4640	07942	Blue PE Med2174	050	11.88	10.18	13.27	21.94	19.06	26.71	609	12.47	12.02	12.96	22.41	20.51	25.03	575	12.93	11.02	14.93	24.01	22.53	27.73	573

EXHIBIT 20

Revolutionizing Orthopaedic Surgery

FiberWire®

Orthopaedic Composite Suture



Exceptional Strength
A unique blend of a UHMW polyethylene multi-filament core with braided polyester jacket gives FiberWire suture exceptional strength, virtually eliminating intraoperative suture breakage. FiberWire #2 is actually stronger than #5 polyester suture.

Resistance to Elongation
The UHMW polyethylene multi-filament core is non braided to provide the greatest resistance to elongation during and after implantation. The braided polyester jacket gives FiberWire handling characteristics similar to polyester suture.

Biocompatibility
Biocompatibility characteristics equivalent to standard polyester suture.

Abrasion Resistance
Over five times more abrasion resistant than standard polyester suture.

Tying Characteristics and Knot Profile
Knots advance smoothly and hold while superior strength allows tighter loop security during knot tying. Tighter loops reduce the knot profile compared to polyester suture.

Variety
Available in sizes ranging from 4-0 to #5 in various designs such as FiberStick, FiberTape, FiberSnare, FiberLoop and TigerWire™.

Safety in Numbers
FiberWire has contributed to successful surgical outcomes in over one million orthopaedic surgical procedures ranging from Achilles tendon repair to rotator cuff repair.

FiberTape™

FiberWire w/10 needle styles

Corkscrew™ FT Suture Anchor w/internal FiberWire eyelet

Bio-SutureTak™ w/FiberWire

Meniscal Viper™ w/2-0 FiberWire

FiberStick™

FiberSnare™

Bio-Corkscrew™ w/TigerTails

FiberLoop™

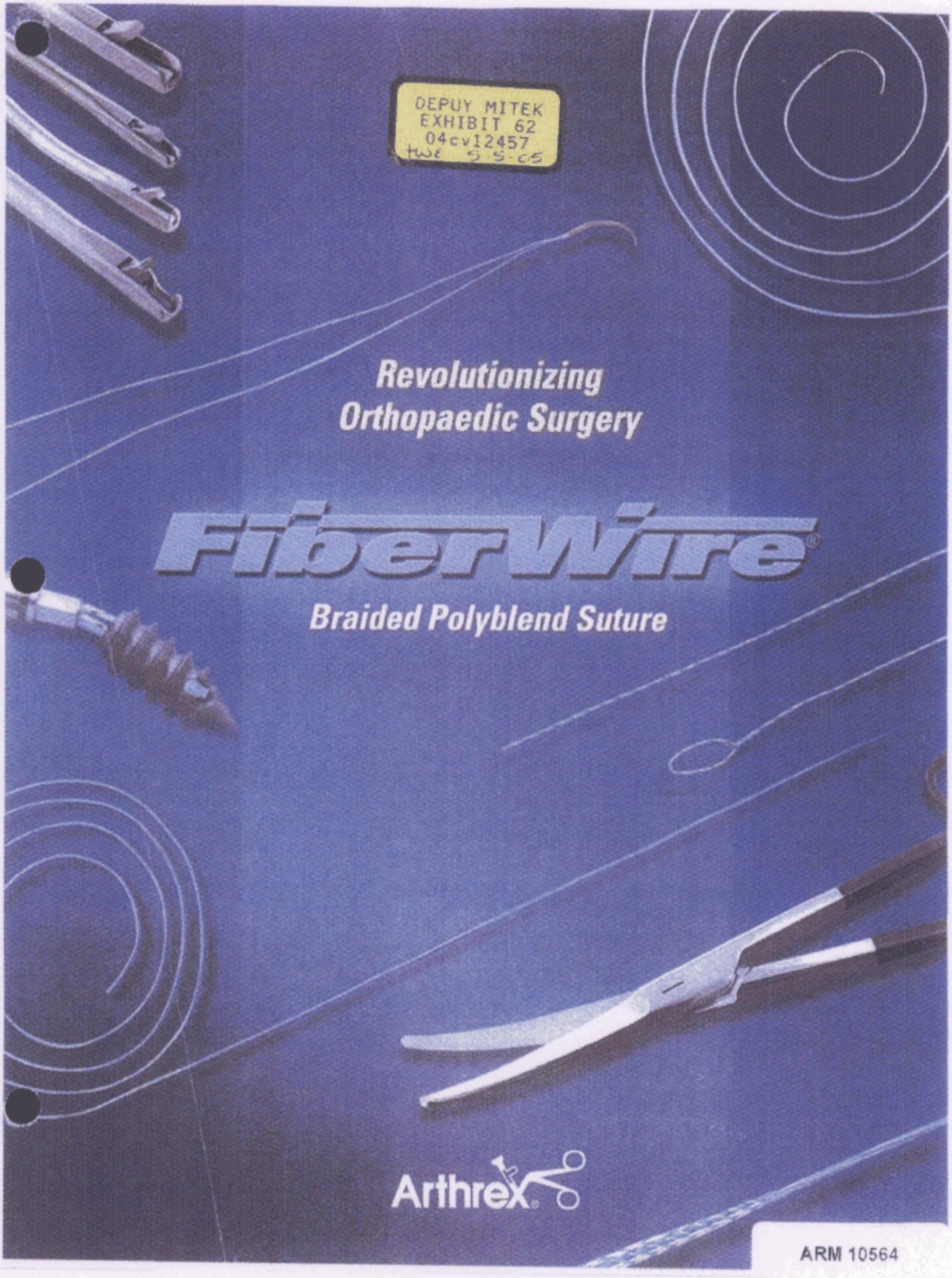
Arthrex®

Innovative Solutions in Minimally Invasive Orthopaedics

1370 Creekside Boulevard
Naples, Florida 34108-1945
Tel: 800-933-7001 Fax: 239-598-5534
www.arthrex.com

U.S. Patent No. 6,716,234

EXHIBIT 21


DEPUY MITEK
EXHIBIT 62
04cv12457
Revolutionizing
Orthopaedic Surgery
FiberWire®
Braided Polyblend Suture
Arthrex®
ARM 10564

Revolutionizing Orthopaedic Surgery

FiberWire® suture is constructed of a long chain polyethylene core with a polyester braided jacket that gives FiberWire superior strength, feel and abrasion resistance that is unequaled in orthopaedic surgery. Suture breakage during knot tying is virtually eliminated, especially critical during arthroscopic procedures. FiberWire represents a major advancement in orthopaedic surgery.

Strength

FiberWire has greater strength than comparable size standard polyester suture. Multiple independent scientific studies document significant increases in strength to failure, stiffness, knot strength and knot slippage with much less elongation[1].

Biocompatibility

Extensive biocompatibility, animal and clinical testing prove that FiberWire demonstrates biocompatibility characteristics equivalent to standard polyester suture. Over two years of successful clinical outcomes in over one million orthopaedic procedures substantiate excellent biocompatibility. Biocompatibility, strength and testing results are available upon request[2].

Tie Ability and Knot Profile

Orthopaedic surgeons enthusiastically endorse FiberWire for its feel and knot tie ability. The first throw stays down, facilitating reproducible tissue repair. Sliding knots advance smoothly easing arthroscopic knot tying procedures. Superior strength allows tighter loop security during knot tying, increasing knot integrity while reducing the knot profile compared to standard polyester suture.

Abrasion Resistance

The UHMW polyethylene core dramatically increases FiberWire abrasion resistance. Surgical procedures that create bone edges, tunnel edges, and articulating surface abrasion areas are appropriate indications for FiberWire. FiberWire is over five times more abrasion resistant than standard polyester suture.

Variety

The FiberWire family has expanded to sizes 4-0 through #5 including new designs such as FiberStick and FiberSnare™ that provide innovative solutions to arthroscopic suture passing. TigerWire® has a black spiral thread for easier arthroscopic visualization, identification, sizing and motion detection. FiberLoop™ is ideal for multistrand tendon repairs.

Safety in Numbers

Trusted by leading orthopaedic surgeons worldwide since its introduction in 2002, FiberWire has contributed to successful surgical outcomes in over one million orthopaedic surgical procedures ranging from Achilles tendon repair to rotator cuff repair. Multiple scientific publications have confirmed the advantages of FiberWire in orthopaedic surgery[3,4].

FiberWire® Suture Family

FiberWire®

FiberWire suture is a new generation of polyester suture with a long chain polyethylene core. FiberWire has greater strength than similar sized polyester suture with superior feel, smooth tie ability and lower knot profile. FiberWire is the ideal suture for most orthopaedic soft tissue repairs, virtually eliminating suture breakage during knot tying.

#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle	AR-7200
#2 FiberWire, 38 inches (blue) w/Reverse Cutting Needle, 36.6 mm 1/2 circle	AR-7202
#2 FiberWire Loop w/Needle for NeedlePunch, 26 inches (blue), 10 mm, straight	AR-7204
#2 FiberWire, 38 inches (blue) w/two Tapered Needles, 26.5 mm 1/2 circle	AR-7205
#2 FiberWire w/two Needles for NeedlePunch, 38 inches (blue), 10 mm, straight	AR-7207
#5 FiberWire, 38 inches (blue)	AR-7210
#5 FiberWire, 38 inches (blue) w/Conventional Cutting Needle, 48 mm 1/2 circle	AR-7211
2-0 FiberWire, 18 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle	AR-7220
2-0 FiberWire, 38 inches (blue)	AR-7221
3-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle	AR-7225
3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle	AR-7227-01
3-0 FiberWire, 18 inches (blue) w/Reverse Cutting Needle, 16.3 mm 3/8 circle	AR-7227-02
4-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 18.7 mm 3/8 circle	AR-7228
4-0 FiberWire, 18 inches (blue) w/Tapered Needle, 12.3 mm 3/8 circle	AR-7230-01
4-0 FiberWire, 18 inches (blue) w/Reverse Cutting Needle, 11.9 mm 3/8 circle	AR-7230-02

TigerWire®

TigerWire suture utilizes the same high strength construction as FiberWire except that it contains a black marker strand in the suture weave. This strand appears as a stripe in the suture making suture identification easier during joint reconstruction and soft tissue repairs.

#2 FiberWire, 38 inches (blue, white/black)	AR-7201
#2 TigerWire, 38 inches (white/black)	AR-7203
#2 TigerWire, 38 inches (white/black) w/two Tapered Needles, 26.5 mm 1/2 circle	AR-7205T

FiberStick and TigerStick™

The stiff "waxed" end of the FiberStick and TigerStick allows convenient and easy advancement through most cannulated instruments or spinal needles, alleviating the need for a monofilament suture or wire suture shuttle. FiberStick and TigerStick come with a thin plastic tube which protects the stiffened suture end until use.

FiberStick, #2 FiberWire, 50 inches (blue) one end stiffened, 12 inches	AR-7209
TigerStick, #2 TigerWire, 50 inches, (white/black) one end stiffened, 12 inches	AR-7209T
2-0 FiberStick, 2-0 FiberWire, 50 inches (blue) one end stiffened, 12 inches	AR-7222

ARM 10566

FiberWire® Suture Family

FiberTape™

FiberTape is an ultra-high strength 2 mm width tape using a similar long chain polyethylene structure as the FiberWire suture. In addition to high demand applications like AC joint reconstruction, the broad footprint of the FiberTape is appropriate for repairs in degenerative cuff tissue where tissue pull-through may be a concern.

FiberTape, 2 mm, 54 inches (blue) each end tapered to #2 FiberWire, 8 inches	AR-7237

FiberLoop™

FiberLoop is a suture option for multistrand tendon repairs. These small diameter looped FiberWire products, in 12 and 20 inch lengths, allow for strong multistrand flexor and extensor tendon repairs while reducing tendon damage from multiple needle passes. FiberLoop is available with 17.9 mm tapered needles to prevent cutting suture while stitching.

4-0 FiberLoop, 4-0 FiberWire, 12 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle	AR-7229-12
4-0 FiberLoop, 4-0 FiberWire, 20 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle	AR-7229-20

FiberSnare™

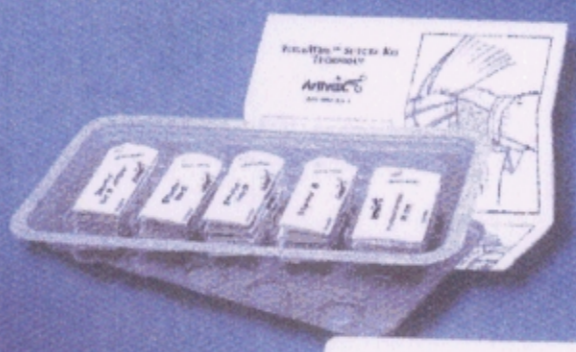
FiberSnare with closed loop provides an easy one step approach to creating a FiberWire loop on the tip of the Bio-Tenodesis Driver. Instead of using a nitinol wire, insert the stiff non-looped end retrograde through the tip of the Bio-Tenodesis Screwdriver. Place the tip of the tendon or tendon graft into the FiberWire loop and cinch the other end around the suture cleat on the back end of the blue Tear Drop Handle. The FiberSnare can also be used as a suture shuttle for passage of traction sutures through bone tunnels.

#2 FiberSnare (green) closed loop, one end stiffened, 12 inches	AR-7209SN

FiberWire® Suture Kit

The FiberWire Suture Kit is available for larger complex soft tissue approximation procedures. This kit contains a total of 18 sutures including three different colored versions of #5 FiberWire for easy suture differentiation, large cutting Spring Eye Free Needles, and #2 FiberWire in one convenient package.

FiberWire Suture Kit	AR-7219



ARM 10567

Suture Anchors with FiberWire®

Suture Anchors

A recent innovation that has had a significant impact on the performance of suture anchors is the availability of FiberWire suture in our suture anchors. The high strength characteristics along with significantly increased abrasion resistance gives the surgeon confidence during crucial knot tying stages where suture breakage is virtually eliminated. Each suture anchor is available with one or two strands of FiberWire and black/white striped TigerWire to facilitate suture differentiation and motion determination.

Our anchors are now available loaded with two strands of a two-toned FiberWire product, TigerTail. TigerTail, available in either blue or white, has a black stripe in one half of the suture. Anchors double loaded with TigerTail will have four visually distinct strands of FiberWire to enhance suture strand differentiation, virtually eliminating suture strand confusion.

Bio-Corkscrew Suture Anchor, 5 mm x 15 mm, w/two #2 TigerTail (a)	AR-1920BT
Bio-Corkscrew Suture Anchor, w/two #2 FiberWire, 5 mm x 15 mm	AR-1920BF
Bio-Corkscrew Suture Anchor, w/two #2 FiberWire, 6.5 mm x 15 mm	AR-1925BF
Bio-Corkscrew Suture Anchor w/Needles, w/#2 FiberWire, 5 mm x 15 mm	AR-1920BNF
Bio-Corkscrew Suture Anchor w/Needles, w/#2 FiberWire, 6.5 mm x 15 mm	AR-1925BNF
Corkscrew II Suture Anchor w/two #2 FiberWire, 5 mm x 15 mm (2 eyelets) (b)	AR-1902SF
Corkscrew Suture Anchor, w/#2 FiberWire, 3.5 mm x 15 mm	AR-1915SF
Corkscrew Suture Anchor, w/#2 FiberWire, 5 mm x 15 mm	AR-1920SF
Corkscrew Suture Anchor, w/#2 FiberWire, 6.5 mm x 15 mm	AR-1925SF
Corkscrew FT Suture Anchor, w/#2 FiberWire, 5 mm x 15 mm (c)	AR-1928SF
Corkscrew FT Suture Anchor w/Needles, w/#2 FiberWire, 5 mm x 15 mm	AR-1928SNF
Bio-FASTak Suture Anchor, w/#2 FiberWire, 3 mm x 11 mm	AR-1324BF
Bio-FASTak Suture Anchor, w/two #2 FiberWire, 3 mm x 11 mm	AR-1324BF-2
Bio-SutureTak Suture Anchor w/#2 FiberWire, 3 mm x 11 mm (d)	AR-1934BF
Bio-SutureTak Suture Anchor w/two #2 FiberWire, 3 mm x 11 mm	AR-1934BF-2
Mini Bio-Anchor w/Needles	AR-1322BNF
Small Bone FASTak Suture Anchor	AR-1372-752SF
FASTak II Suture Anchor w/Handle and #2 FiberWire, 2.8 mm 11.7 mm	AR-1324HF
FASTak II Suture Anchor w/#2 FiberWire, 2.8 mm x 11.7 mm	AR-1324SF
FASTak Suture Anchor w/#2 FiberWire, 2.4 mm x 11.7 mm	AR-1322SXF

ARM 10568

FiberWire® Accessories

Suture Cutters

The Suture Cutters were designed to facilitate arthroscopic suture cutting with specially designed cutting jaws, with and without visual control.

The Suture Cutter's precision jaws prevent knot cutting by leaving a length of reproducible suture tail, 3 mm for the 4.2 mm outer diameter cutter and 1 mm for the 2.75 mm outer diameter cutters, without direct visual control. These cutters have a special locking device to prevent premature suture cutting. The blunt tip of the cutter is excellent for knot pushing.

The Open Ended Suture Cutter was designed to speed up the suture cutting process. This cutter allows for quick and efficient suture tail cutting under direct visual control through the same or alternate cannula or portal. The notch on the side of the cutter tip automatically guides the suture tails into the front cutting slot for an accurate cut from any angle.

All Suture Cutters are recommended for cutting FiberWire.

Suture Cutter, 4.2 mm, straight	AR-12250
2.0 Suture Cutter, 2.75 mm, straight	AR-11790
2.0 Suture Cutter, 2.75 mm, 15° up curve	AR-11791
Suture Cutter, Open Ended, Left Notch	AR-11794L

FiberWire Scissor

The FiberWire Scissor was designed to cut any size or style suture, especially FiberWire, in open surgical cases where an arthroscopic suture cutter is not necessary. With its specially designed cutting edges, it can cut FiberWire cleanly and effortlessly without frayed edges. The color coded handle facilitates instrument differentiation in large instrument packs.

FiberWire Scissor	AR-11796

FiberWire Tensioner

The FiberWire Tensioner provides controlled tensioning of FiberWire loops during knot tying when reapproximating soft tissue. The blunt tip keeps the knot in place while the tensioning wheel and spring mechanism gently tension the loop to tighten the repair. It is appropriate for use in conjunction with #5 FiberWire during tuberosity reapproximation for proximal humerus fractures.

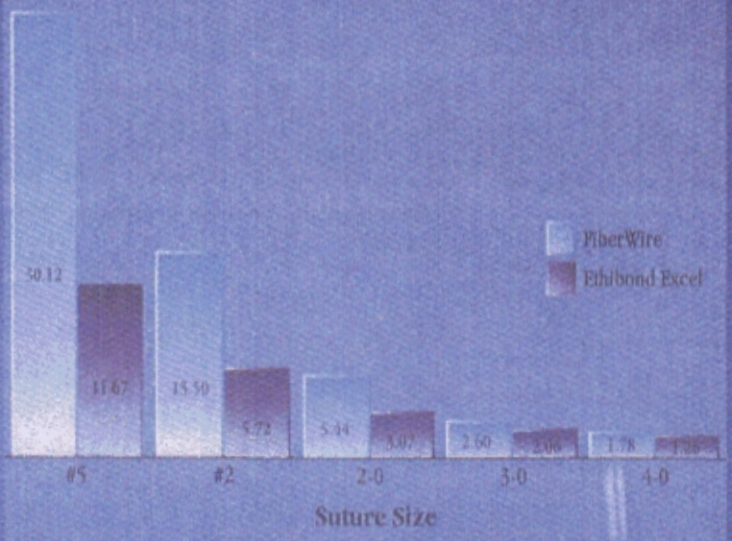
It is recommended that the FiberWire Tensioner be used in conjunction with sliding-locking knots. Once the FiberWire is passed through all planes of tissue/bone, the appropriate sliding knot is tied and advanced to the tissue level. One limb of the FiberWire suture is passed up through the cannulation of the FiberWire Tensioner shaft, with the aid of a Suture Passing Wire, and loaded into the slot and locking post on the tensioning wheel to keep it in place. The tensioning wheel is then turned in a counter-clockwise fashion as the tension meter is read. Once the desired amount of tension/reduction is achieved, the tensioner is removed and three reverse half-hitches can be thrown to secure the fixation.

FiberWire Tensioner	AR-1929
Suture Passing Wire	AR-1255-18
#5 FiberWire, 38 inches	AR-7210

ARM 10569

Knot Strength Comparison

Peak Load in KG Force (average)



**Data on file*

References:

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3. Lo I KY, Burkhart SS. *Biomechanical Principles of Arthroscopic Repair of the Rotator Cuff.* Operative Techniques in Orthopaedics 2002; 12-3:140-155.
4. Deakin M, Stubbs D, Goldberg J, Bruce W, Gillies RM, Walsh WR. *Effect of Suture Type, Anchor and Testing Orientation of the Static Properties of Suture Anchors.* A Poster Presentation, #1536. 50th Annual Meeting of the Orthopaedic Research Society.

Contact Arthrex Customer Service at

800-934-4404

for a free sample of any size FiberWire
for your surgical evaluation.

Feeling is believing....

ARM 10570

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U.S. PATENT NO. 6,716,234

Arthrex FiberWire® Reference Chart

FiberWire®

Suture Size	Suture Length	Description	Needle Dimensions	Needle Reference
#5 (7 metric)	38 inches	1 strand (blue)		
#5 (7 metric)	38 inches	1 strand (blue) with Conventional Cutting Needle	48 mm 1/2 circle	CS-1 (376218C)
#2 (5 metric)	38 inches	1 strand (blue) with Tapered Needle	26.5 mm 1/2 circle	T-5 (305001C)
#2 (5 metric)	38 inches	2 strands (blue, white/black)		
#2 (5 metric)	38 inches	1 strand (blue) w/Reverse Cutting Needle	36.6 mm 1/2 circle	C-13 (365051A)
#2 (5 metric)	38 inches	1 strand (white/black) TigerWire		
#2 (5 metric)	26 inches	1 strand (blue) w/closed Loop w/Needle for NeedlePunch	10 mm	
#2 (5 metric)	38 inches	1 strand (blue) w/two Tapered Needles	26.5 mm 1/2 circle	T-5 (305001C)
#2 (5 metric)	38 inches	1 strand (white/black) TigerWire w/two Tapered Needles	26.5 mm 1/2 circle	T-5 (305001C)
#2 (5 metric)	38 inches	1 strand (blue) w/two Needles for NeedlePunch	10 mm	
2-0 (3 metric)	18 inches	1 strand (blue) w/Tapered Needle	17.9 mm 3/8 circle	T-13 (382874A)
2-0 (3 metric)	38 inches	1 strand (blue)		
3-0 (2 metric)	18 inches	1 strand (blue) w/Diamond Point Needle	26.2 mm 3/8 circle	DE-14 (832641S)
3-0 (2 metric)	18 inches	1 strand (blue) w/Tapered Needle	15 mm 3/8 circle	T-43 (382802A)
3-0 (2 metric)	18 inches	1 strand (blue) w/Reverse Cutting Needle	16.3 mm 3/8 circle	C-22 (392489A)
4-0 (1.5 metric)	18 inches	1 strand (blue) w/Diamond Point Needle	18.7 mm 3/8 circle	DE-10 (8329XXA)
4-0 (1.5 metric)	18 inches	1 strand (blue) w/Tapered Needle	12.3 mm 3/8 circle	T-12 (382227A)
4-0 (1.5 metric)	18 inches	1 strand (blue) w/Reverse Cutting Needle	11.9 mm 3/8 circle	C-17 (392264A)

FiberStick

#2 (5 metric)	50 inches	1 strand (blue) one end stiffened, 12 inches		
#2 (5 metric)	50 inches	1 strand (black/white) one end stiffened, 12 inches		
2-0 (3 metric)	50 inches	1 strand (blue) one end stiffened, 12 inches		

FiberTape™

	54 inches	2 mm (blue) each end tapered to #2 FiberWire, 8 inches		

FiberSnare™

#2 (5 metric)	26 inches	1 strand (green) stiffened w/closed loop, 12 inches		

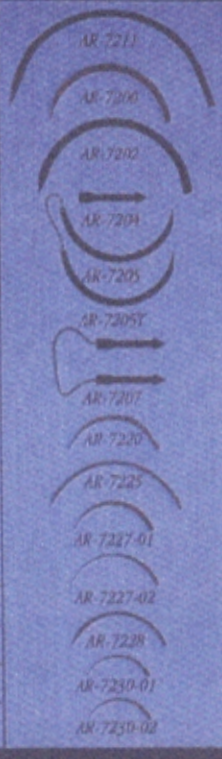
FiberLoop™

4-0 (1.5 metric)	12 inches	1 strand (blue) w/Tapered Needle	17.9 mm 3/8 circle	T-13 (382874A)
4-0 (1.5 metric)	20 inches	1 strand (blue) w/Tapered Needle	17.9 mm 3/8 circle	T-13 (382874A)

FiberWire® Suture Kit

#5 (7 metric)	38 inches	4 strands (blue), 4 strands (white) and 4 strands (green)	60 mm 3/8 circle, 80 mm 1/2 circle	
#2 (5 metric)	38 inches	6 strands (blue) w/Tapered needle		

ARM 10572

Recommended Uses	Supplied	Cat Number	Box Color	Actual Size of Needles
Use with FiberWire Tensioner for Tendon, Ligament or Soft Tissue Repair, AC Joint Repair	12/box	AR-7210		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7211		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7200		
Reload suture anchors, use with Viper	12/box	AR-7201		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7202		
Reload Suture Anchors	12/box	AR-7203		
Rotator Cuff Repair	10/box	AR-7204		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7205		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7205T		
Rotator Cuff Repair	10/box	AR-7207		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7220		
Meniscal Repair	12/box	AR-7221		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7225		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7227-01		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7227-02		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7228		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7230-01		
Tendon, Ligament or Soft Tissue Repair	12/box	AR-7230-02		
Rotator Cuff Repair, Glenoid Labrum Repair and Capsular Plication	5/box	AR-7209		
Rotator Cuff Repair, Glenoid Labrum Repair and Capsular Plication	5/box	AR-7209T		
Rotator Cuff Repair, Glenoid Labrum Repair, Capsular Plication, TFCC Repair and Meniscal Repair	5/box	AR-7222		
AC Joint Repair	6/box	AR-7237		
Use with Bio-Tenodesis Driver for Tendon Snare	12/box	AR-7209SN		
Multistrand Tendon Repairs	12/box	AR-7229-12		
Multistrand Tendon Repairs	12/box	AR-7229-20		
Tuberosity Fixation	1/box	AR-7219		
Soft Tissue Reconstruction				

ARM 10573

EXHIBIT 22

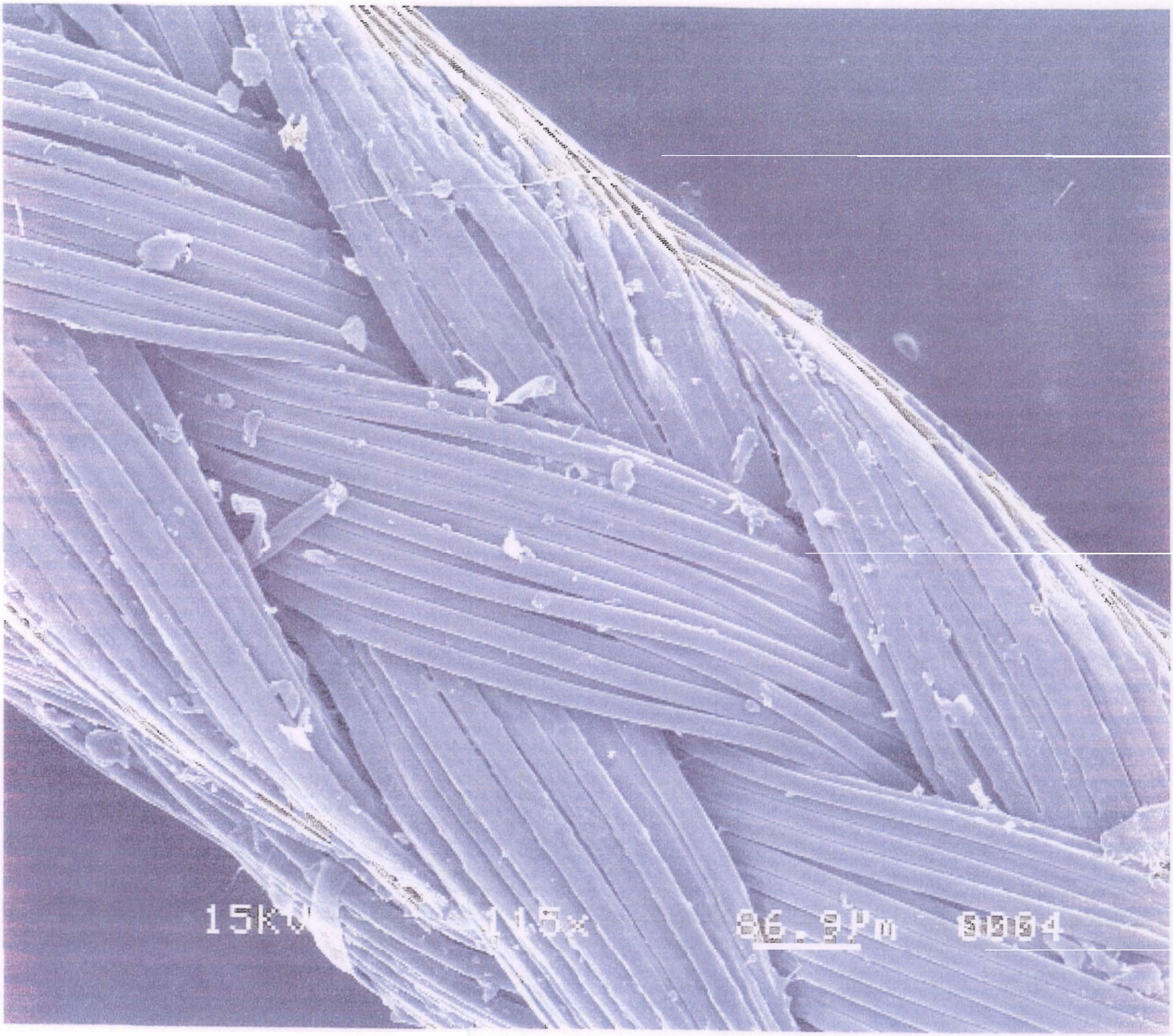


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EXHIBIT 23

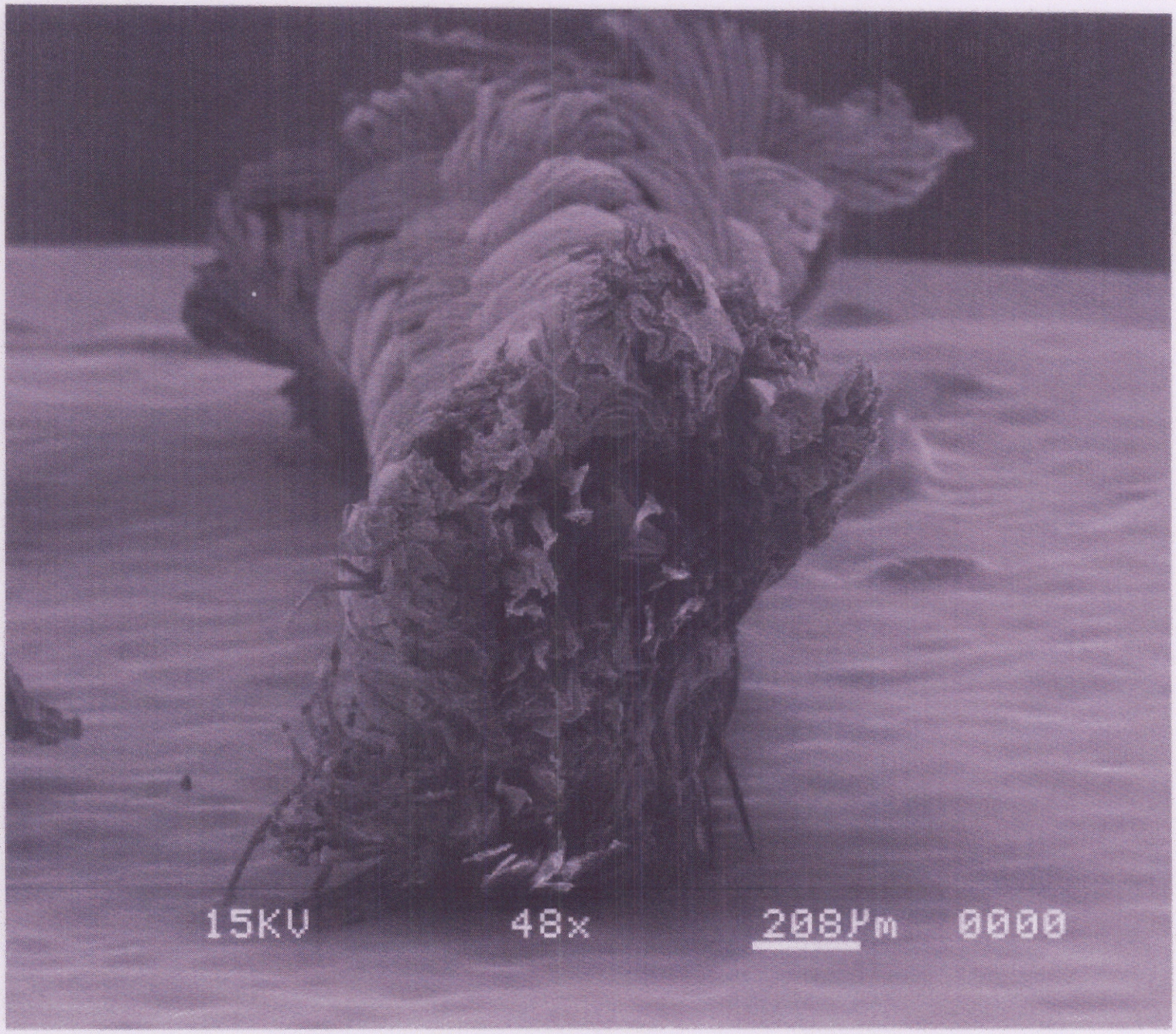

EXHIBIT 24